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Eberle et al.

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(54) **PROCESS FOR APPLYING A CUSHION MATERIAL TO AN ARTICLE**

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(52) **U.S. Cl.** **264/512**; 264/102; 264/257; 264/258; 264/266; 264/267; 264/325; 156/245

(58) **Field of Search** 264/510, 511, 264/512, 101, 102, 257, 258, 266, 267, 299, 319, 313, 324, 325, 219; 156/245

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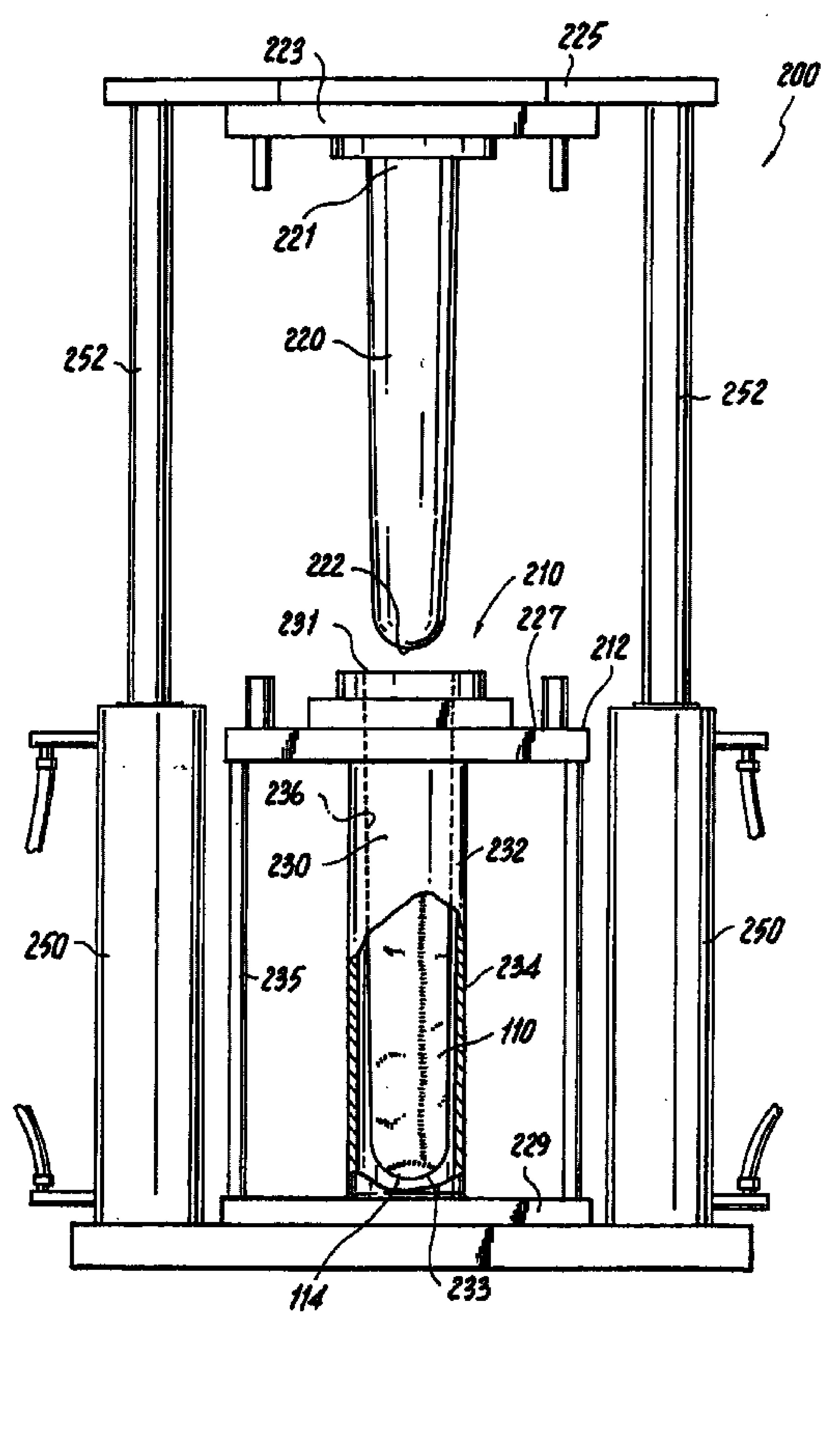
(57) **ABSTRACT**

A process for forming a cushion layer of a preselected thickness on an inside of a prosthetic liner body is provided and includes the steps of introducing the liner body into a mold cavity; disposing a sufficient amount of cushioning material into the inside of the liner and directing a mandrel into the inside of the liner body. The driving action of the mandrel causes the cushioning material to be dispersed between the mandrel and the liner body, thereby forming the cushioning layer of preselected thickness.

40 Claims, 13 Drawing Sheets



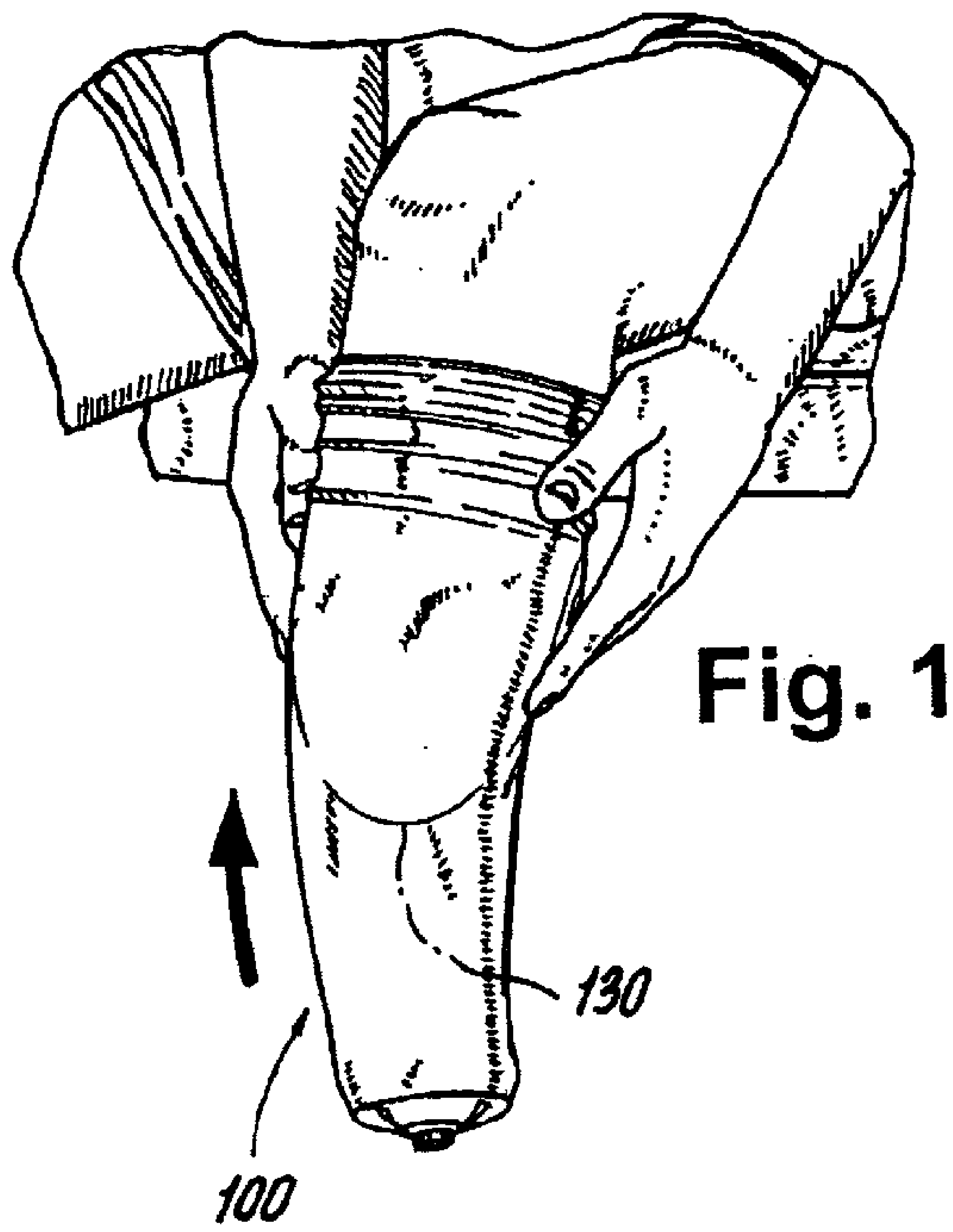
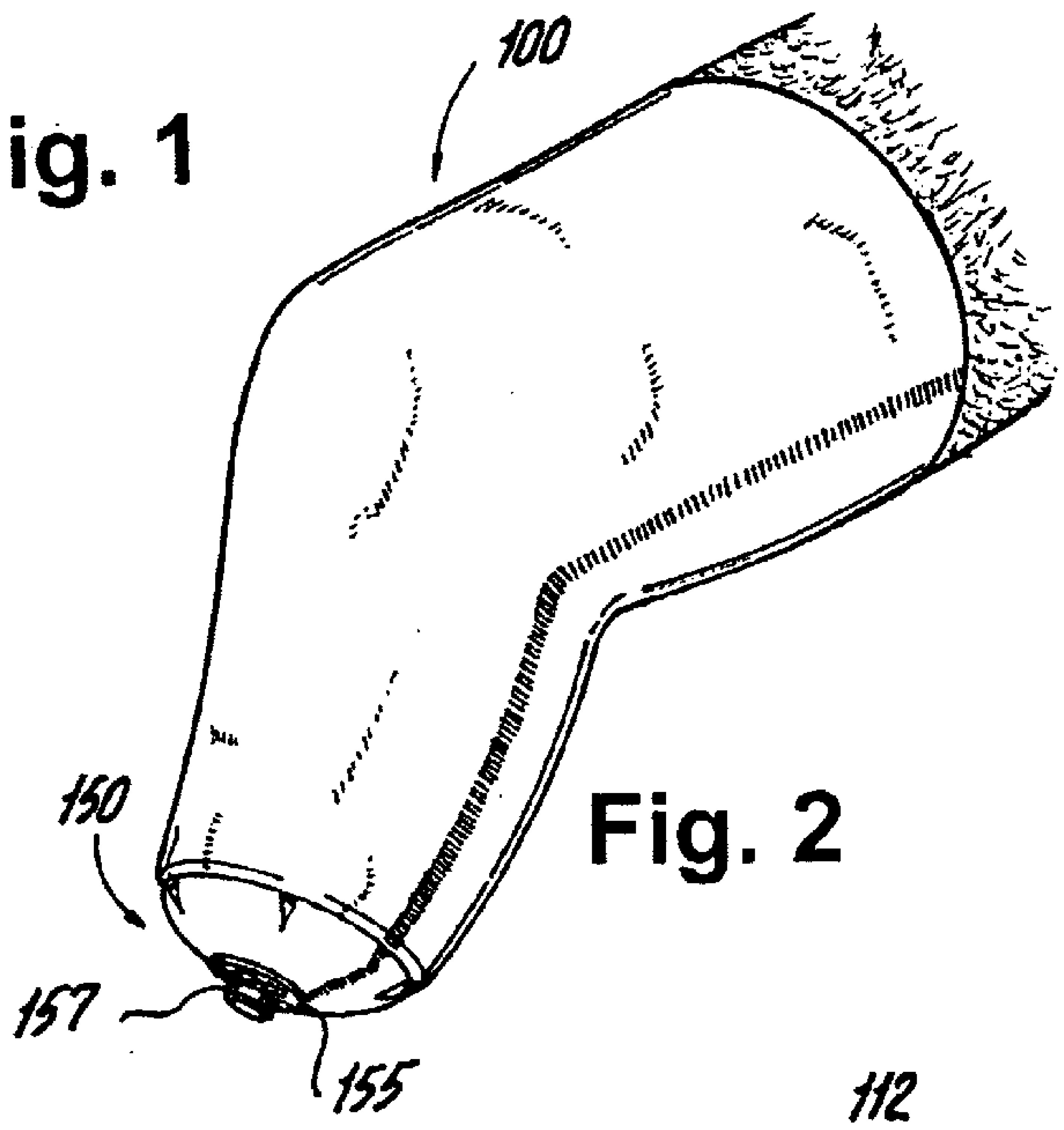


Fig. 1



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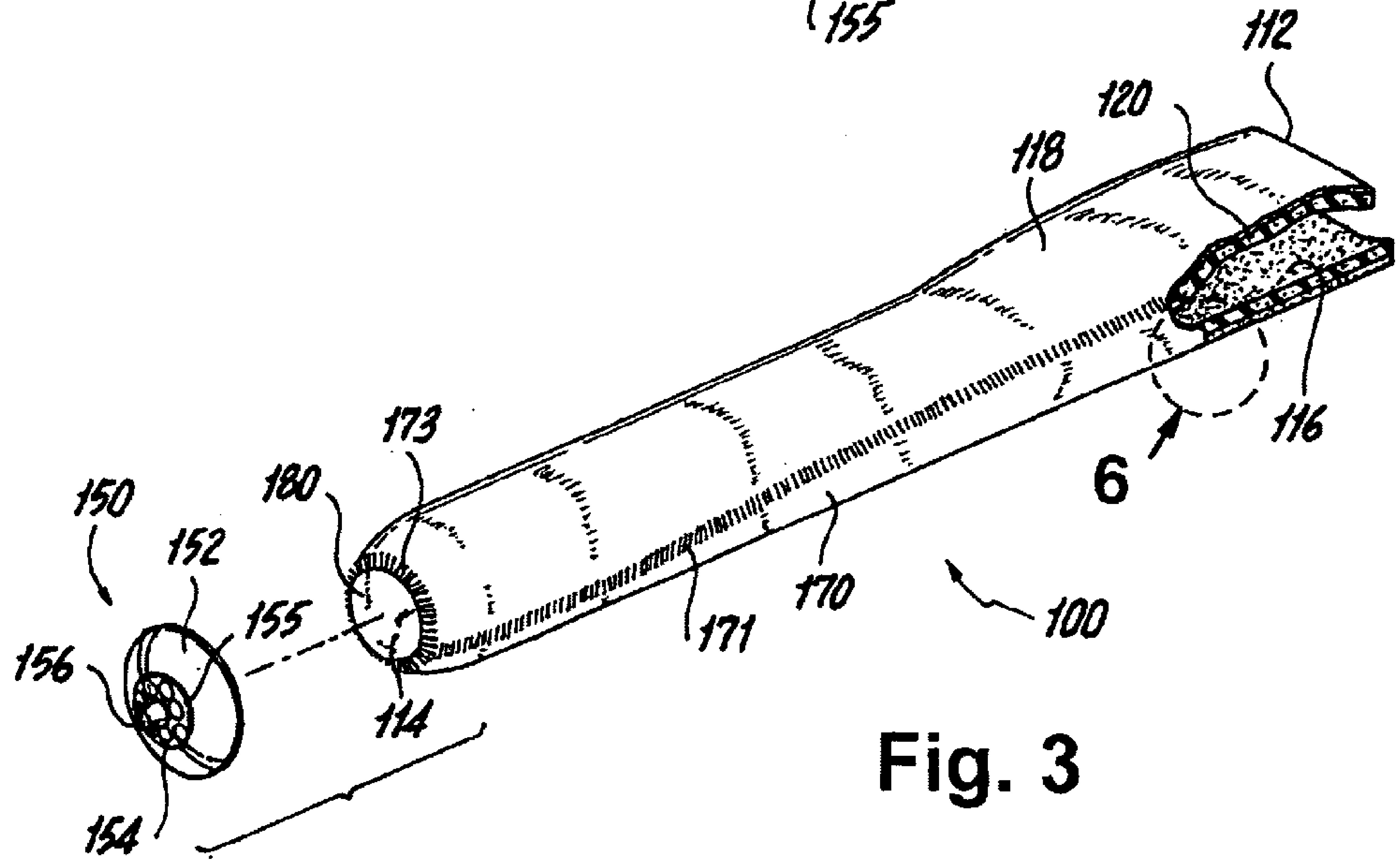

Fig. 3

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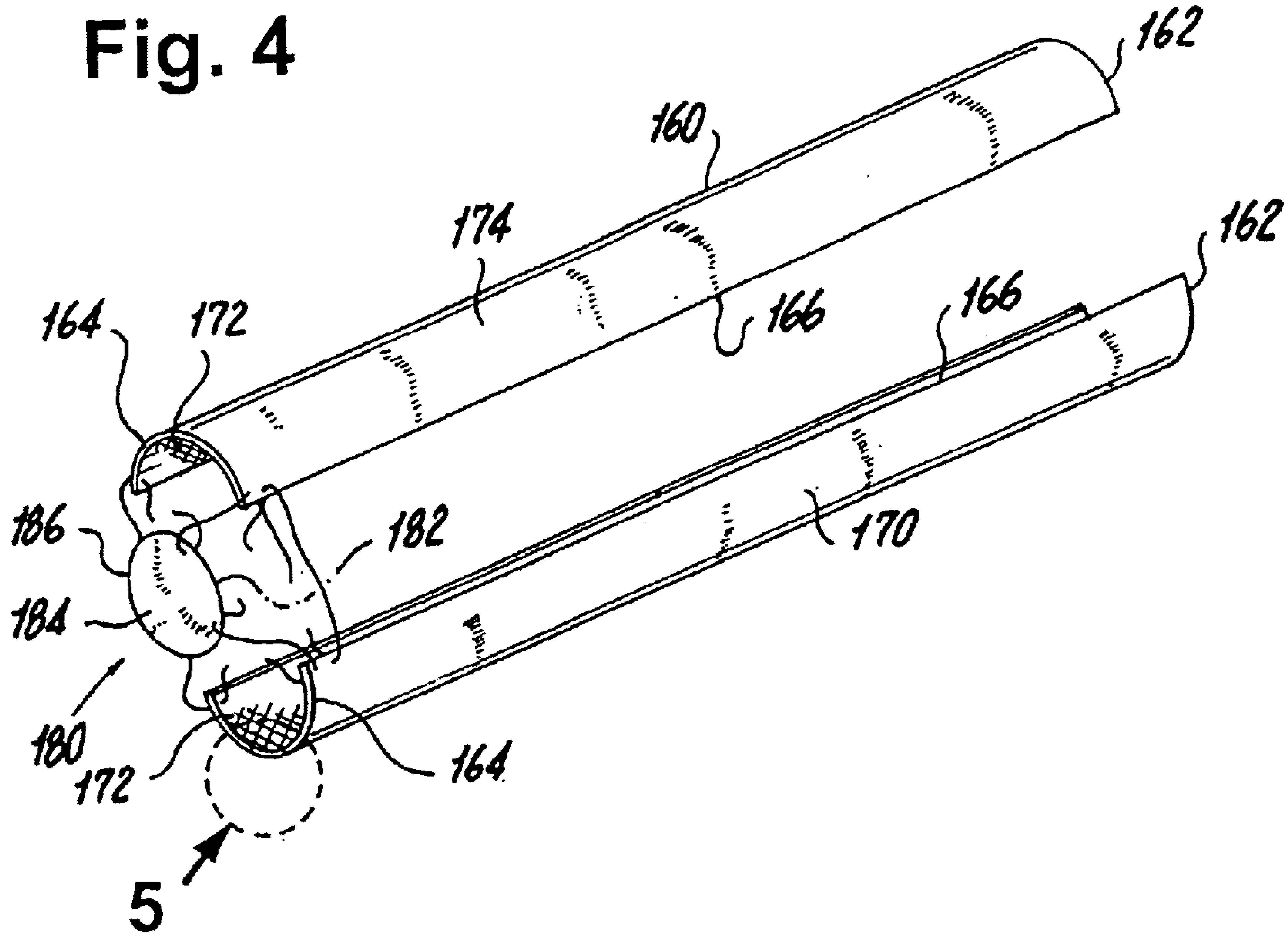

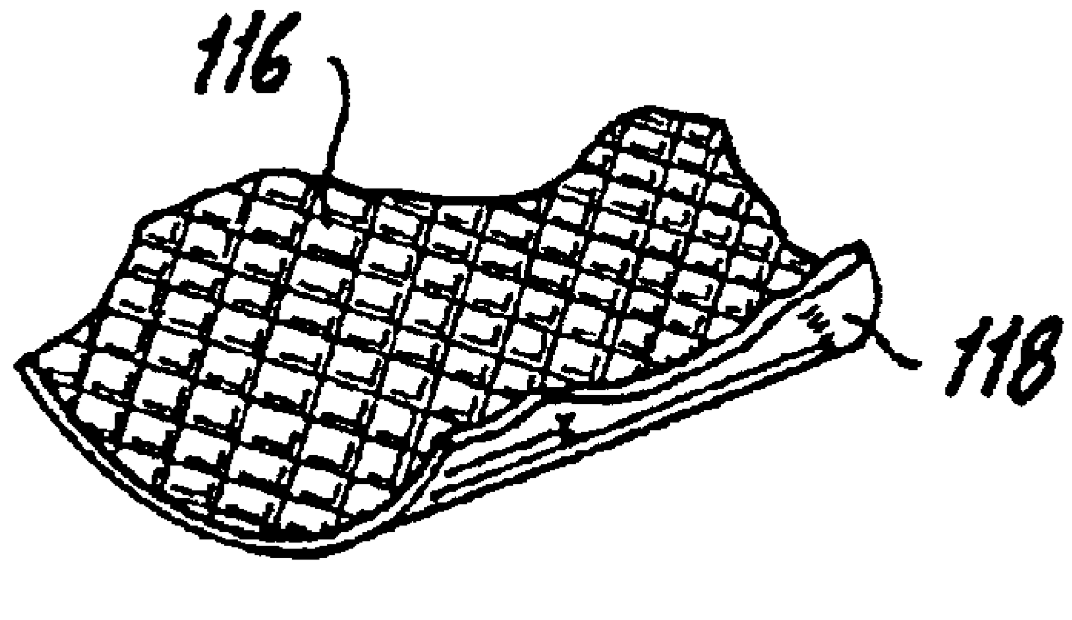

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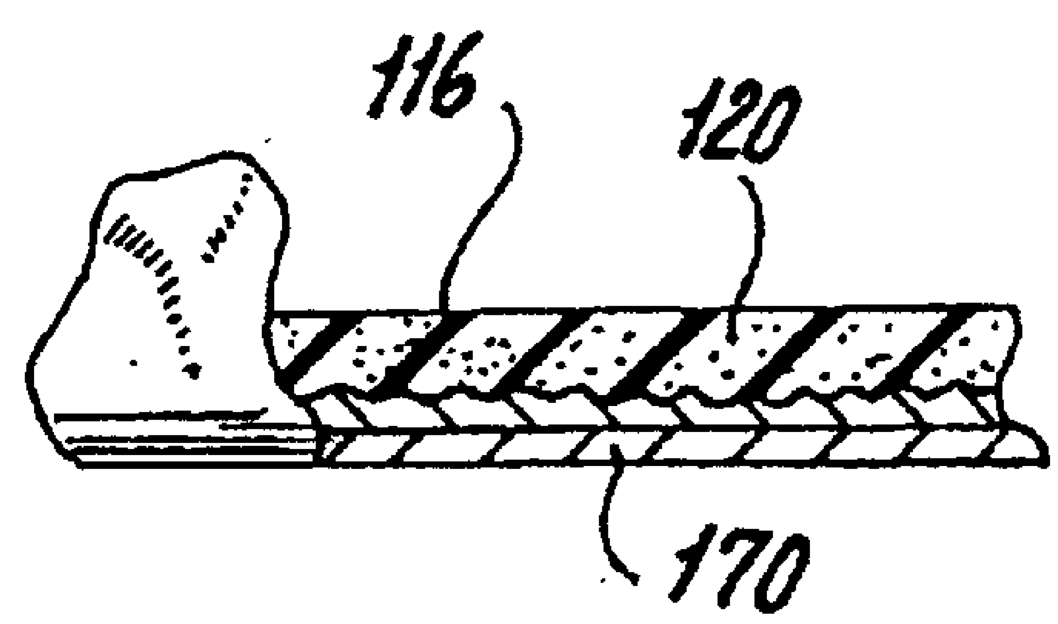

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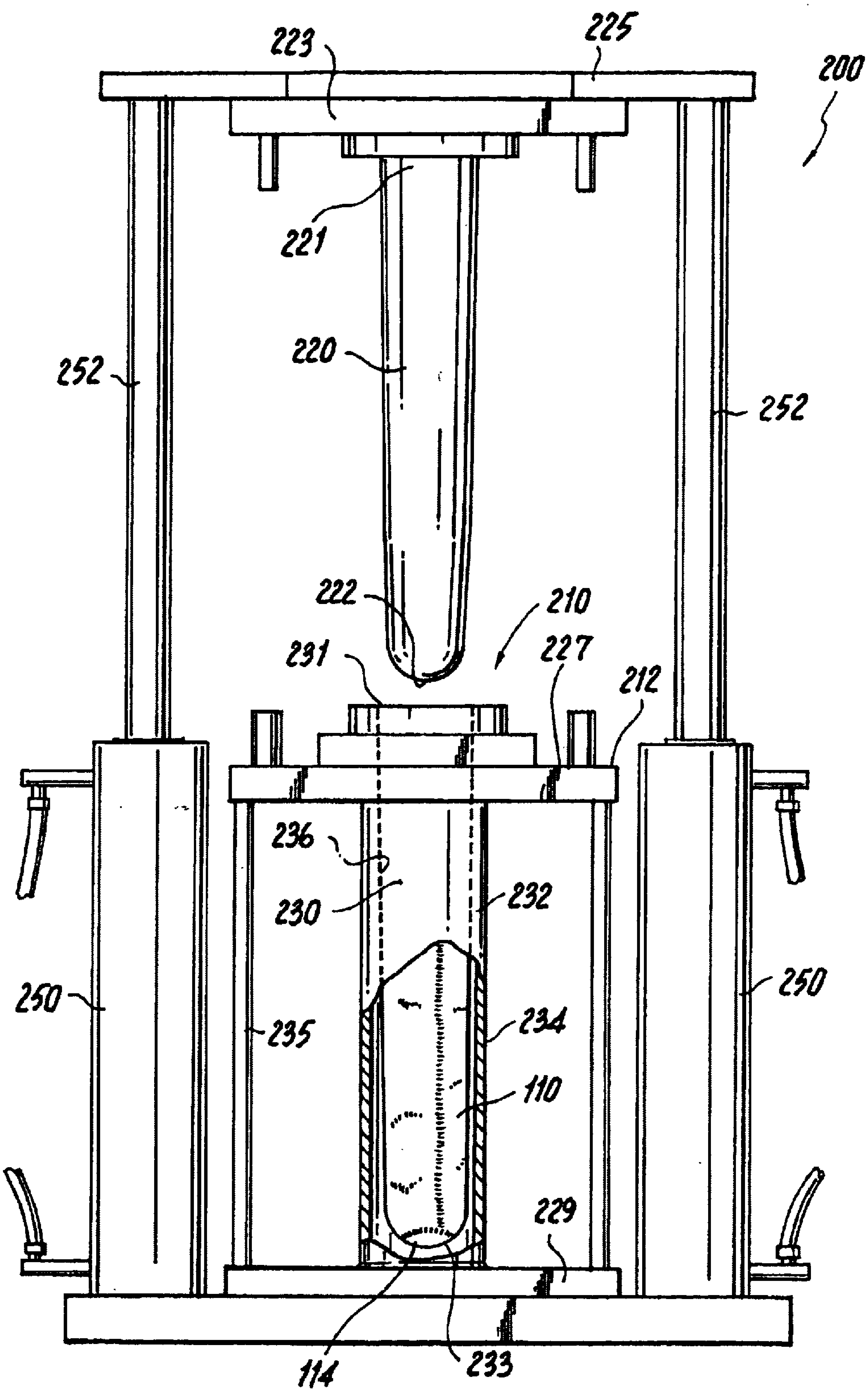
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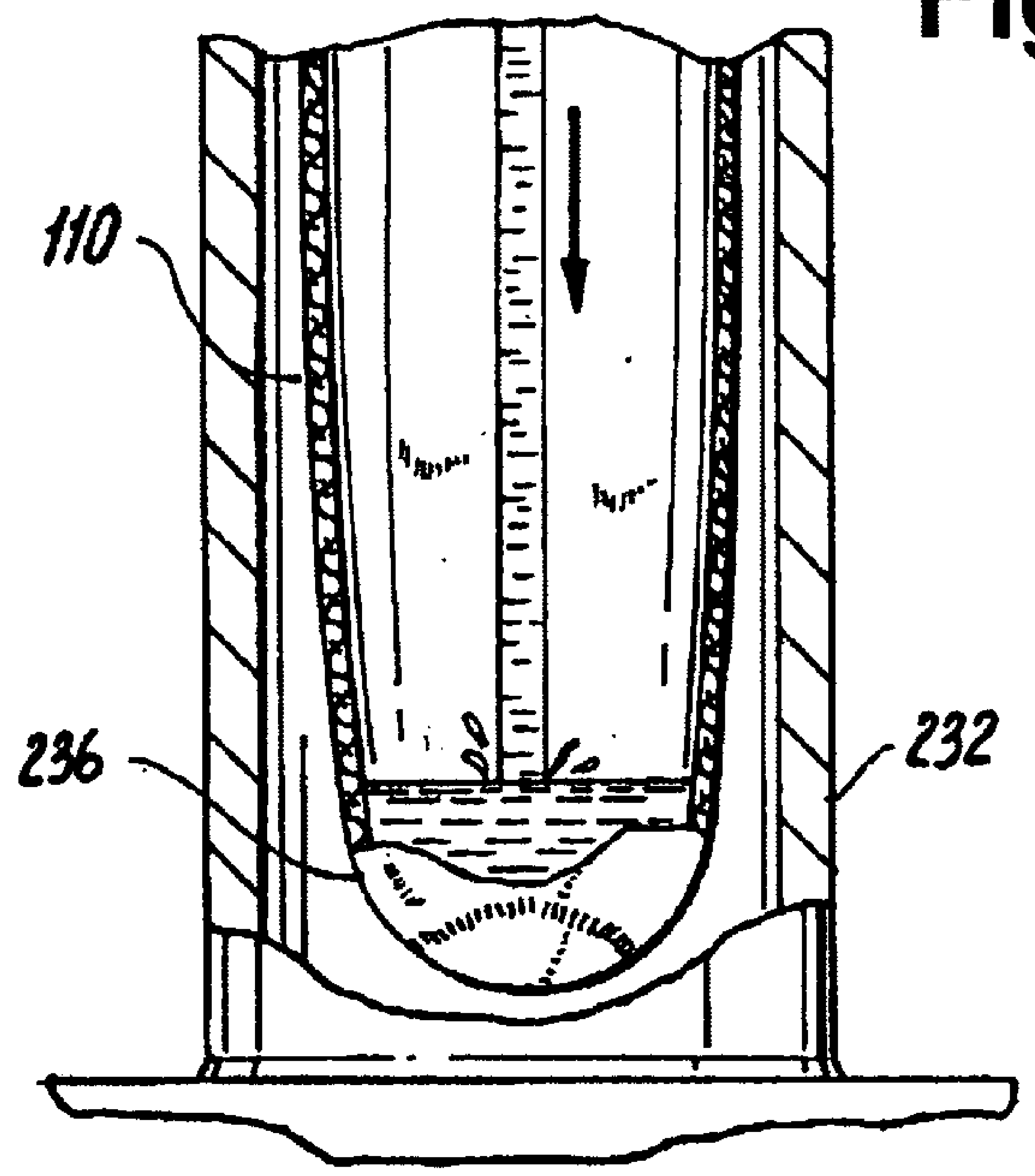
Fig. 7

Fig. 8



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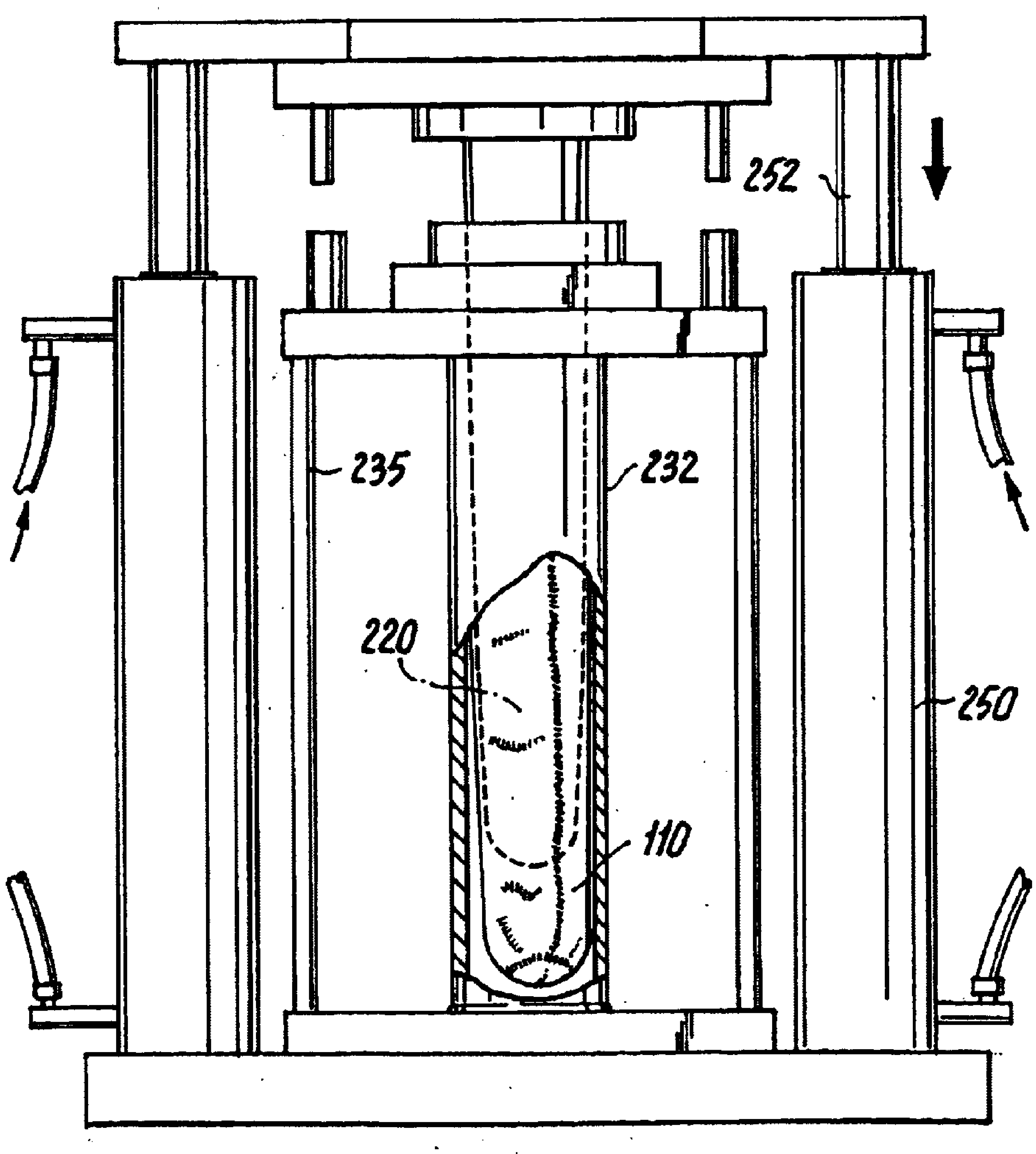

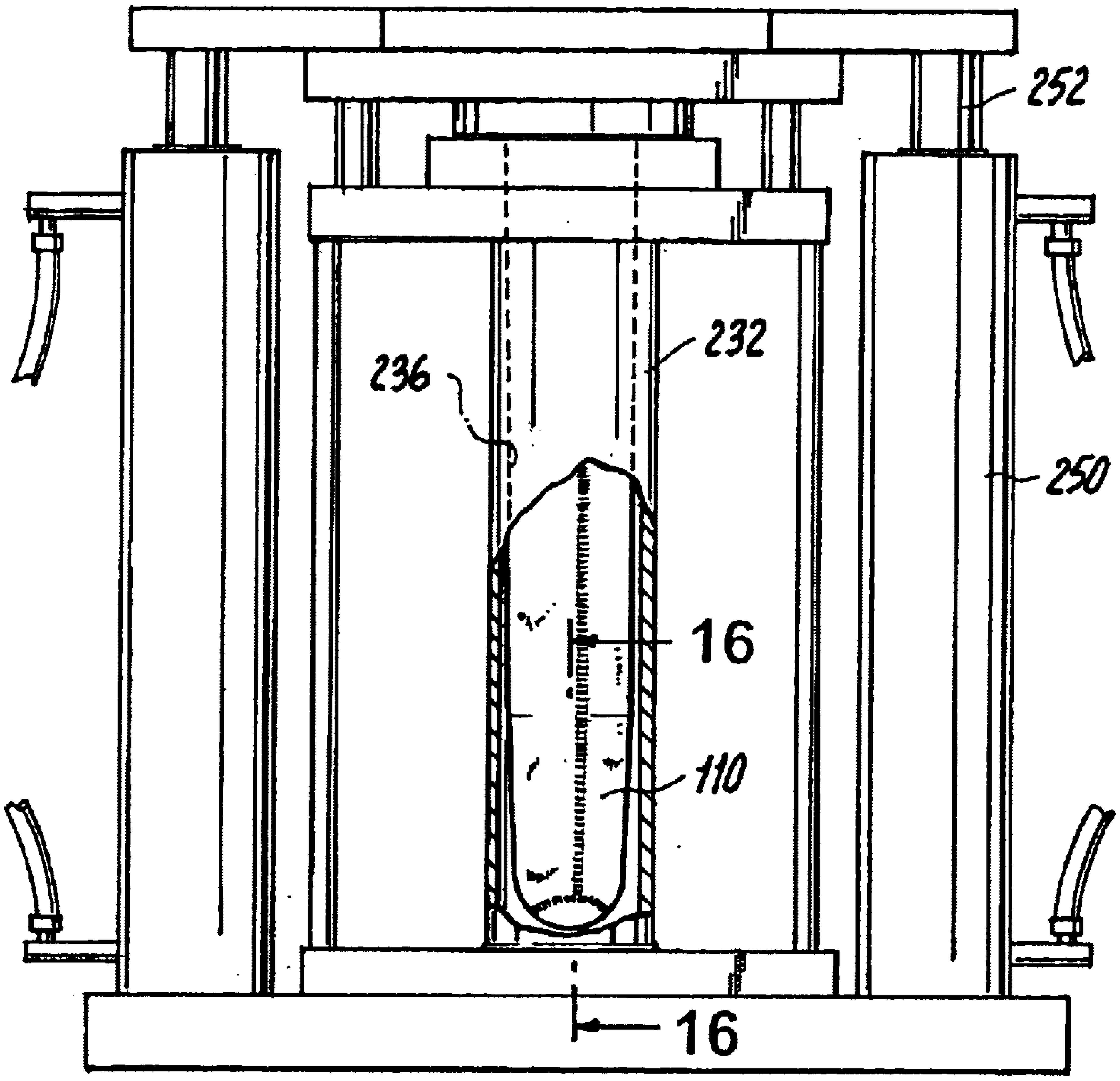

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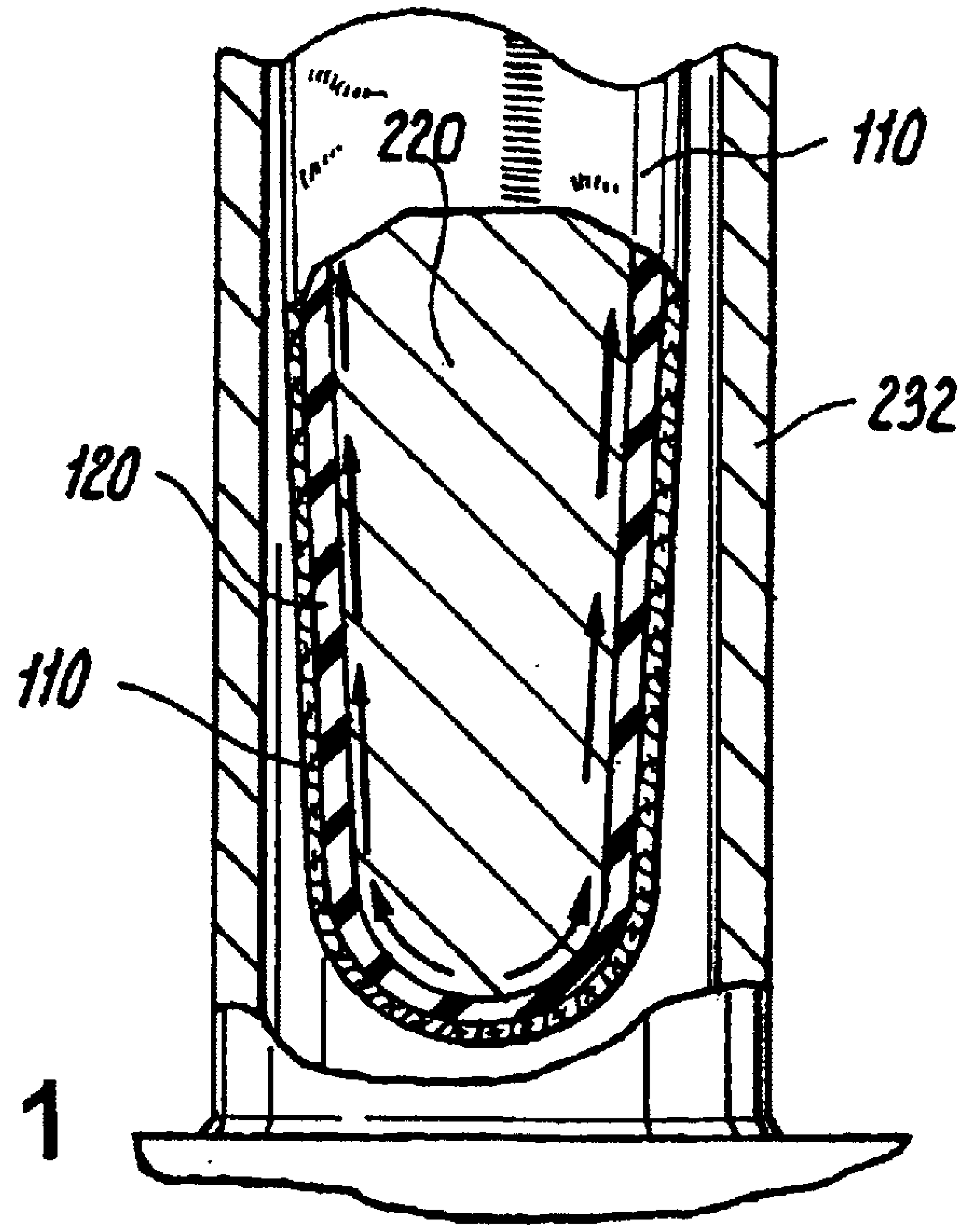

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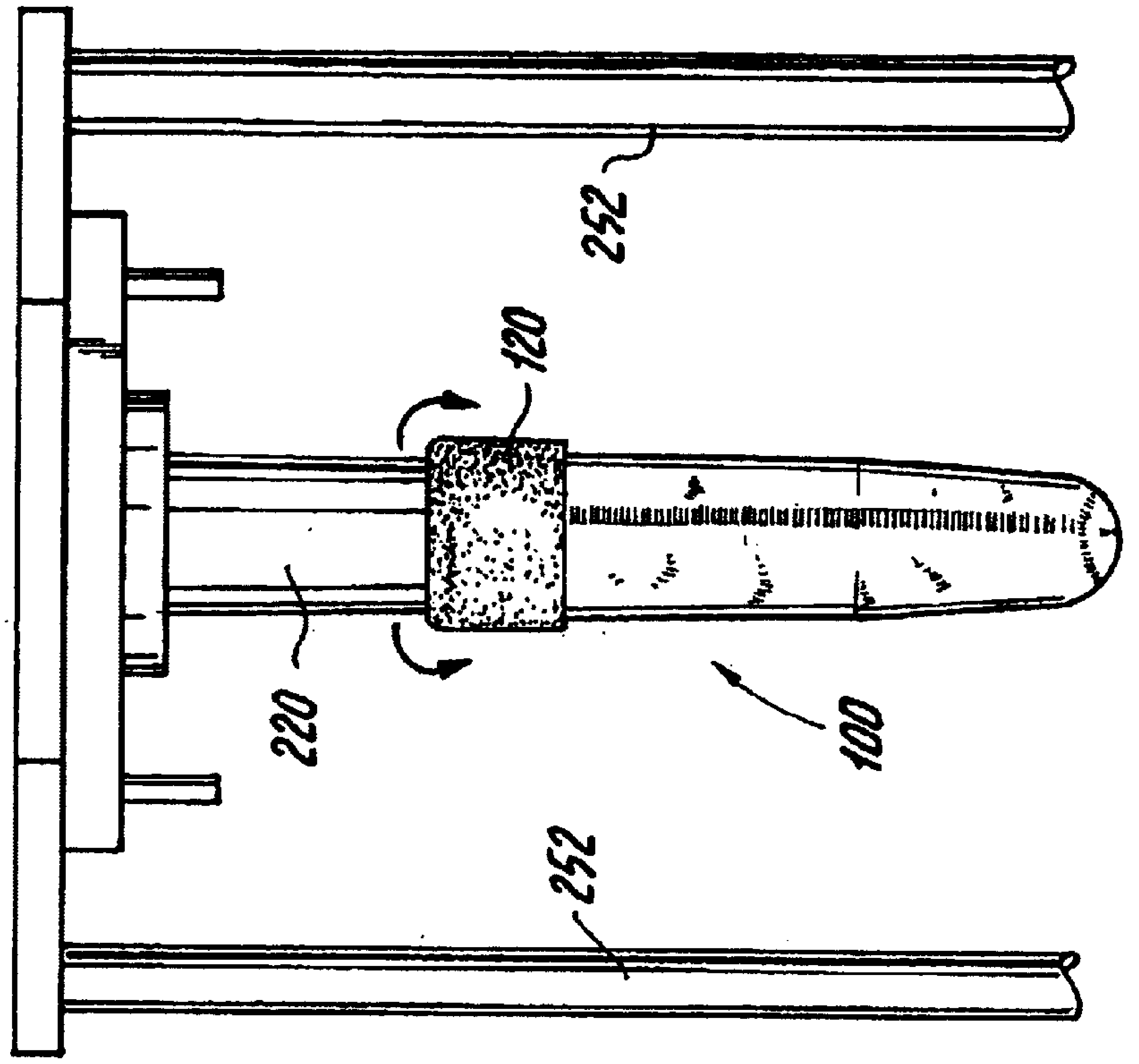

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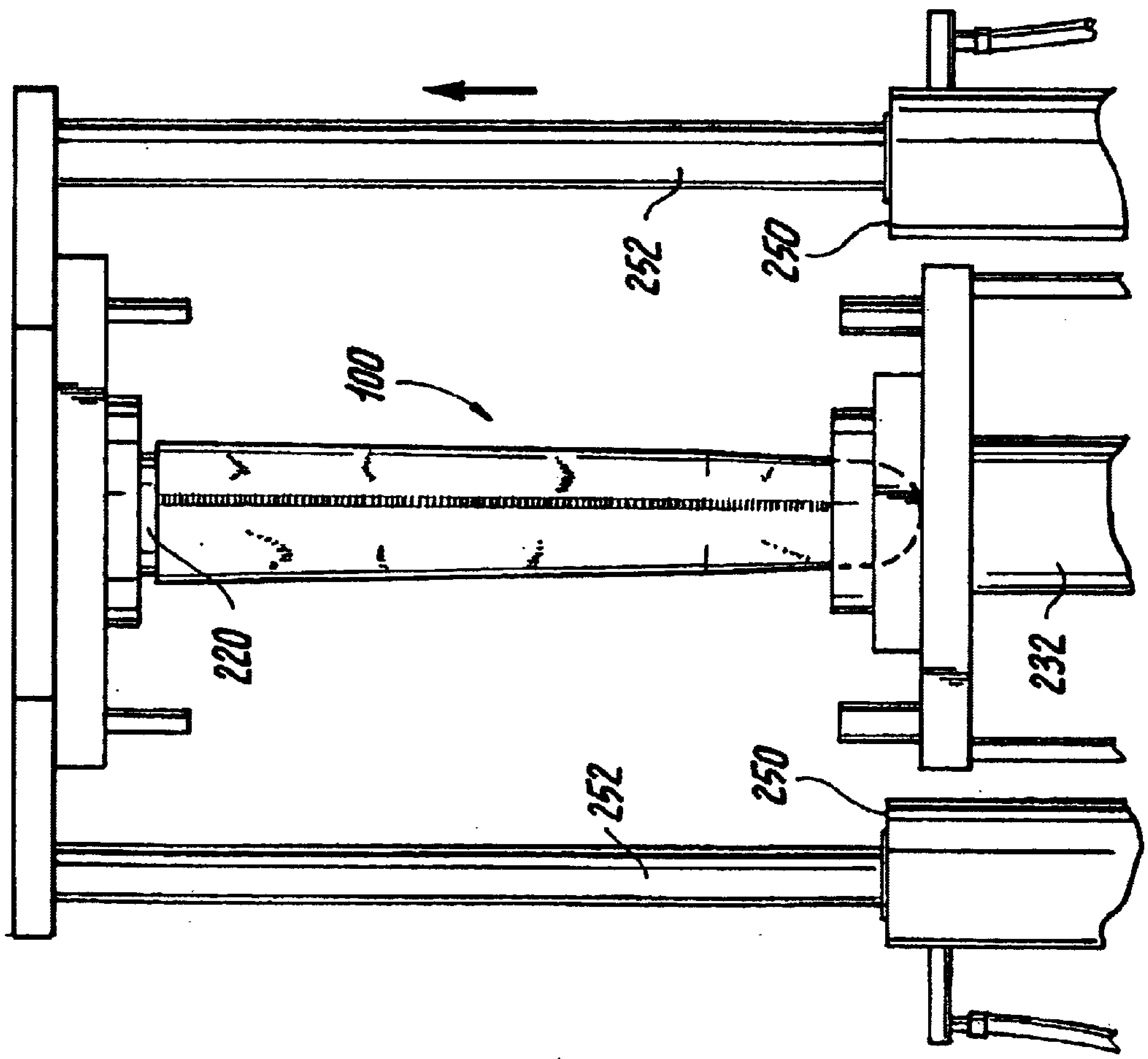

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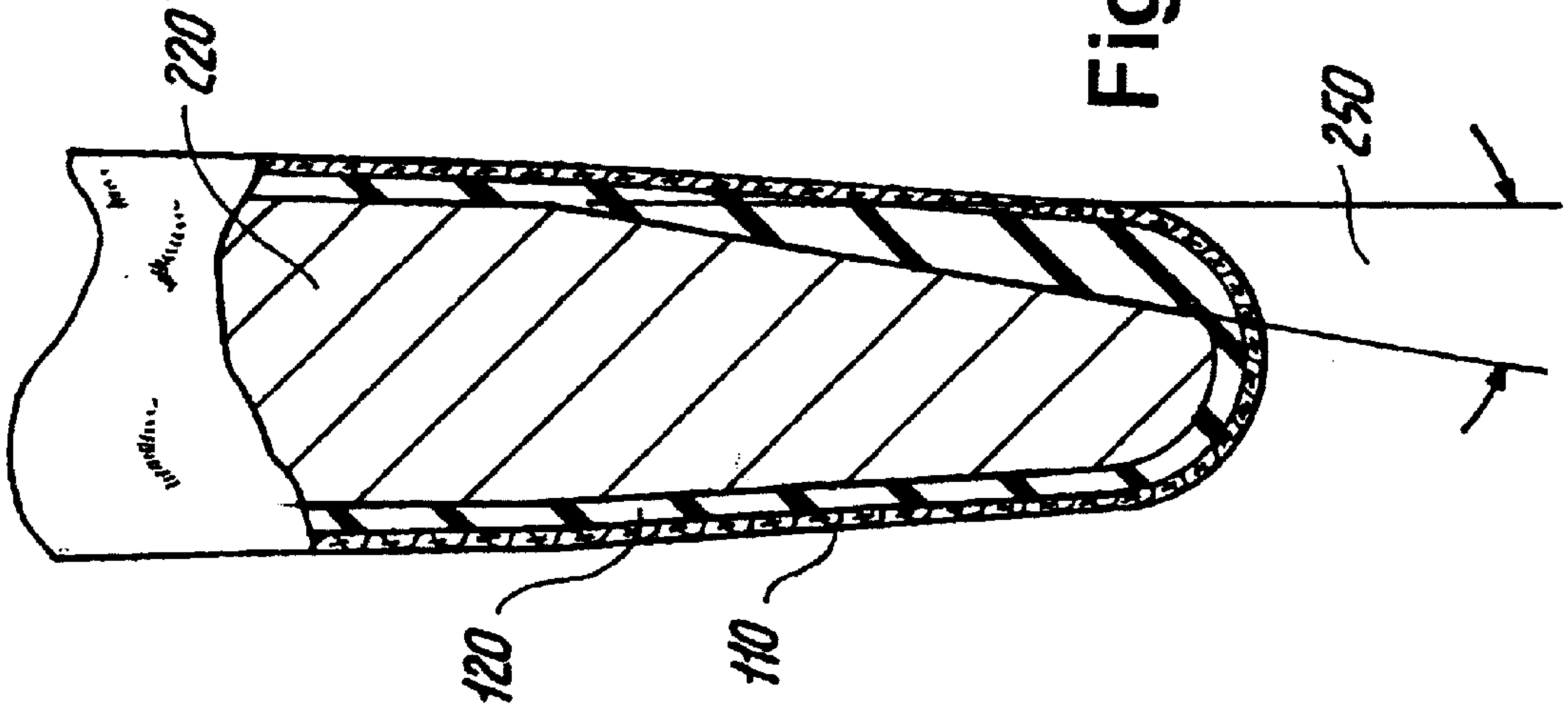
Fig. 15



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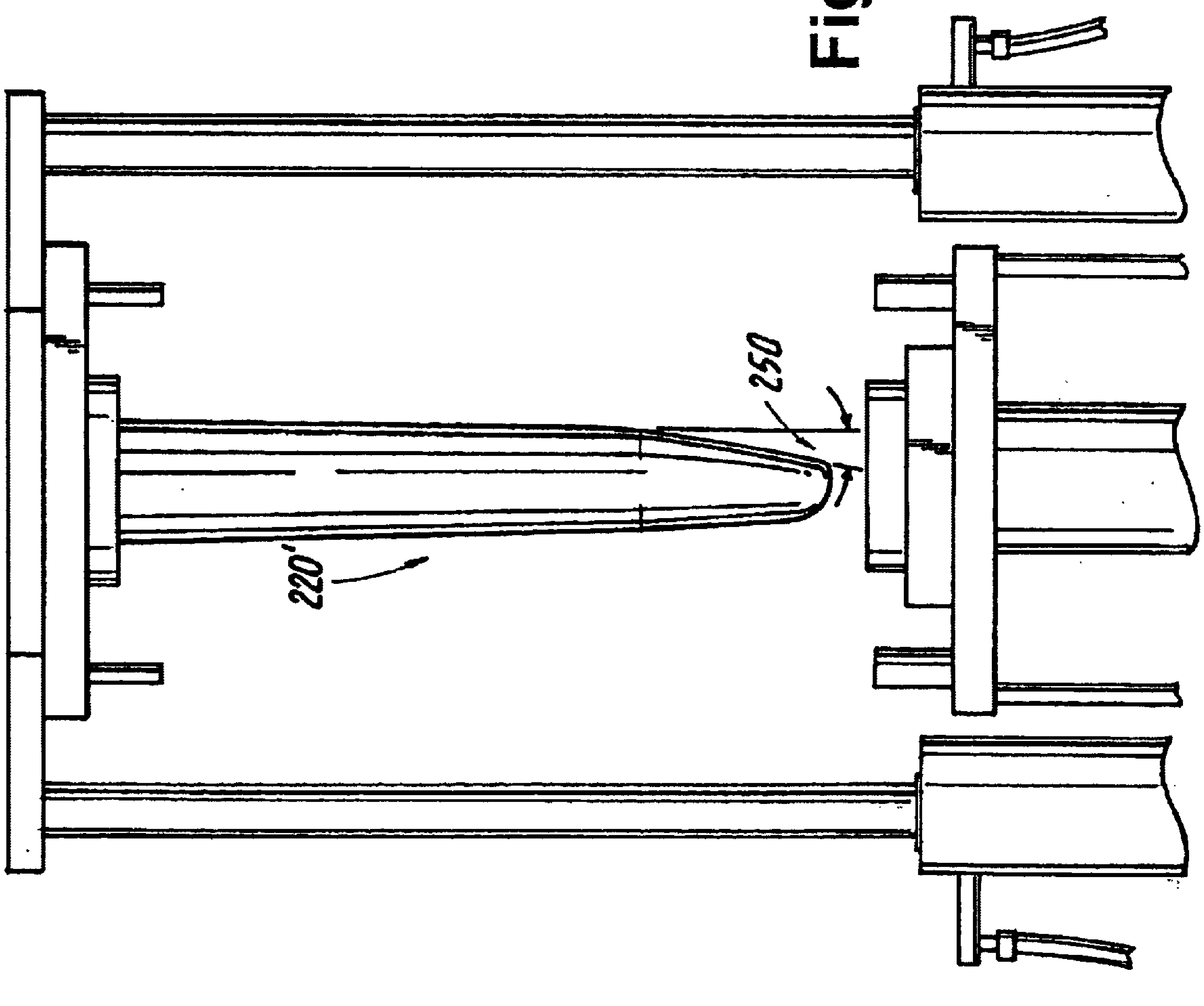

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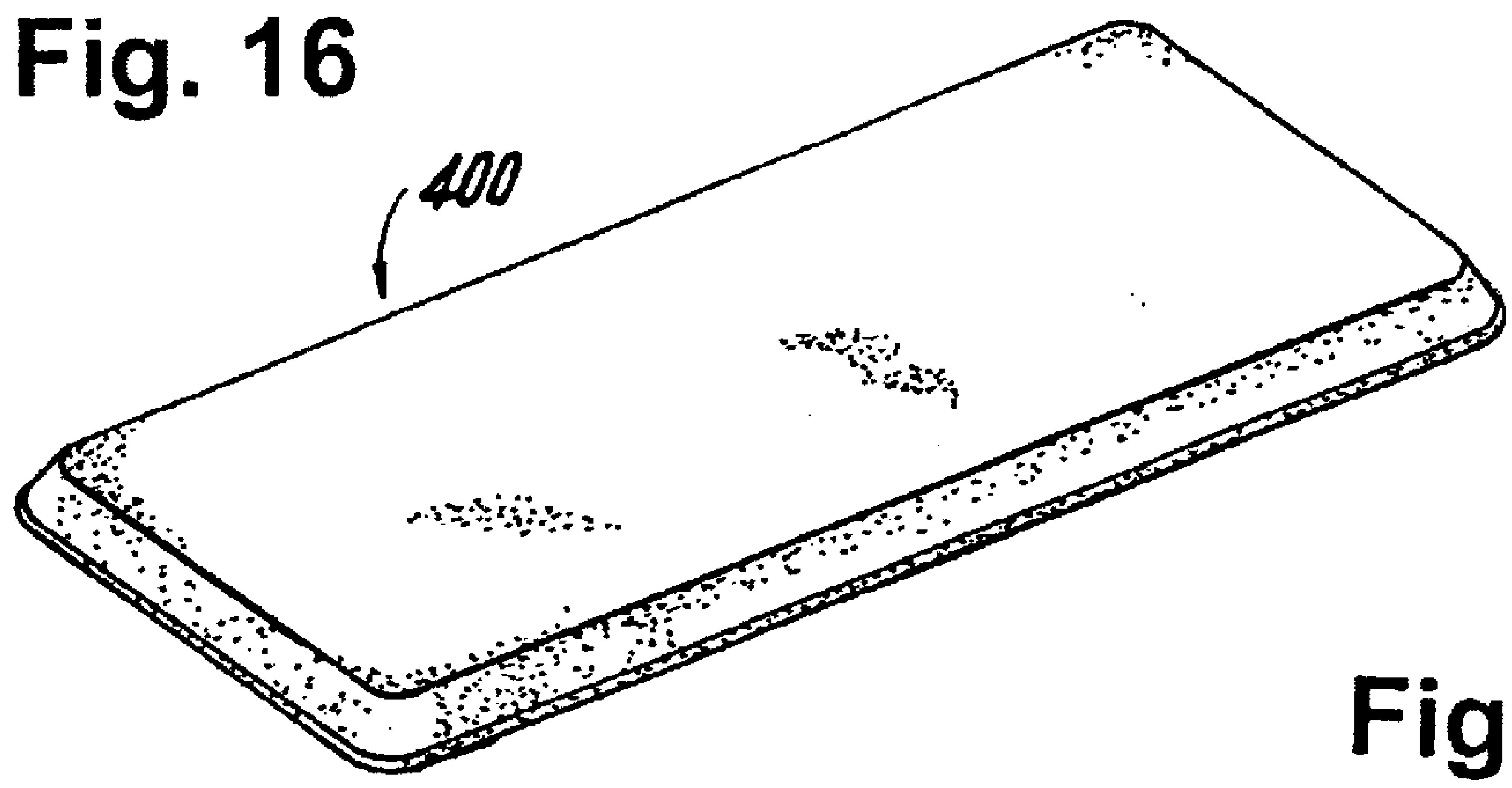

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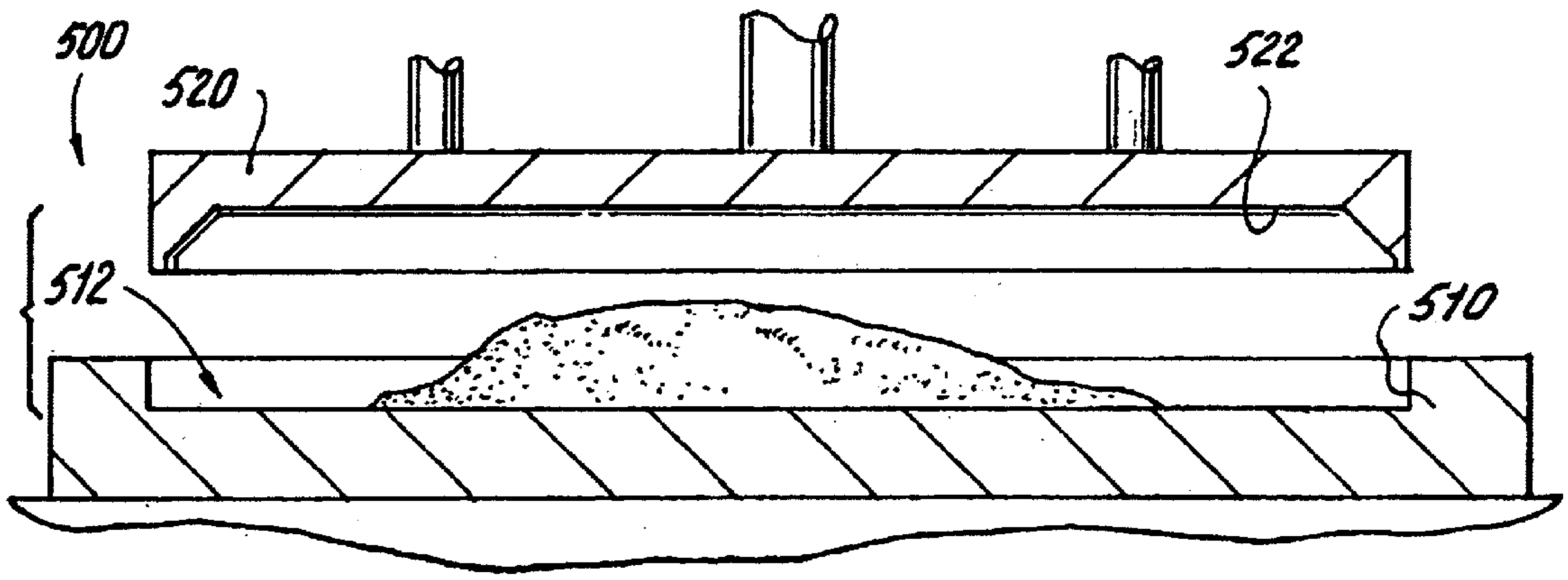

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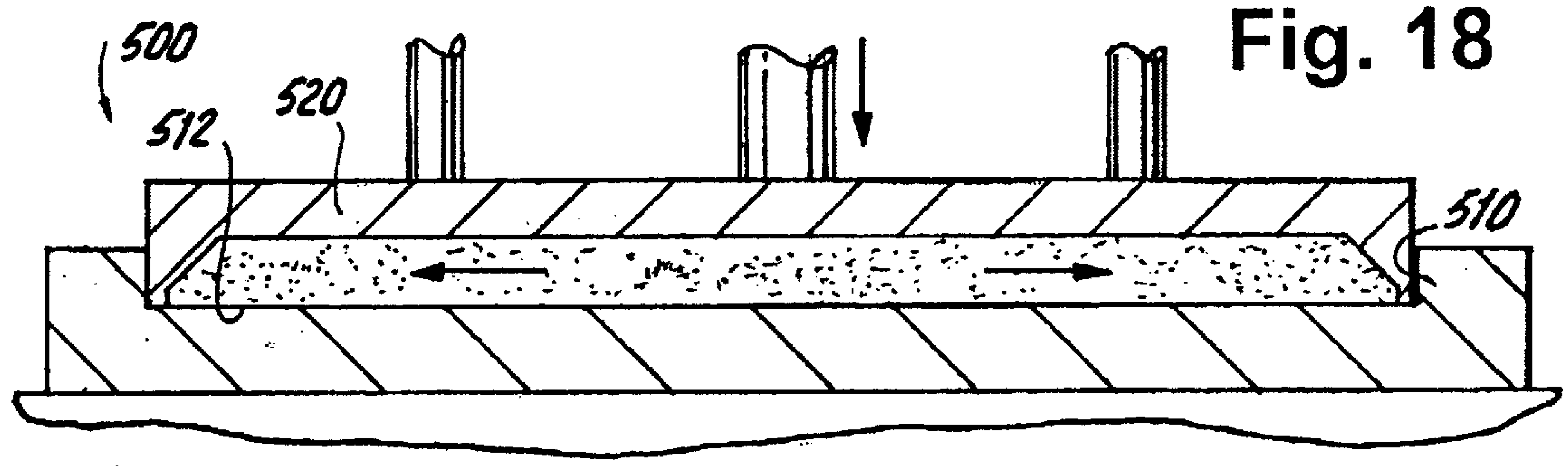

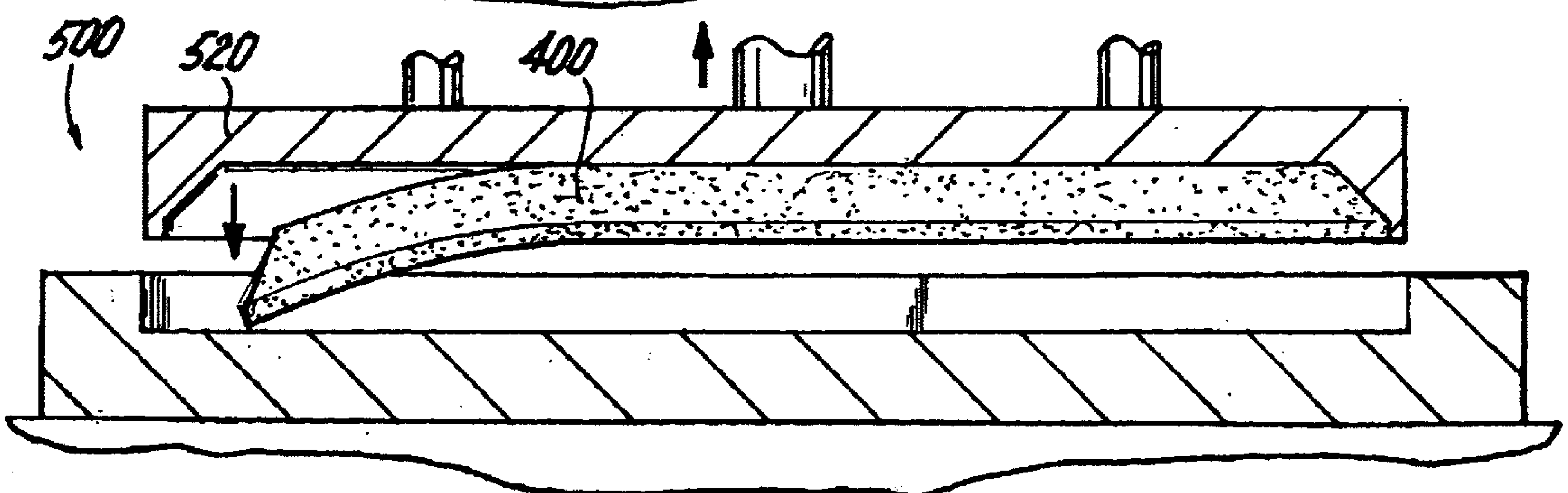

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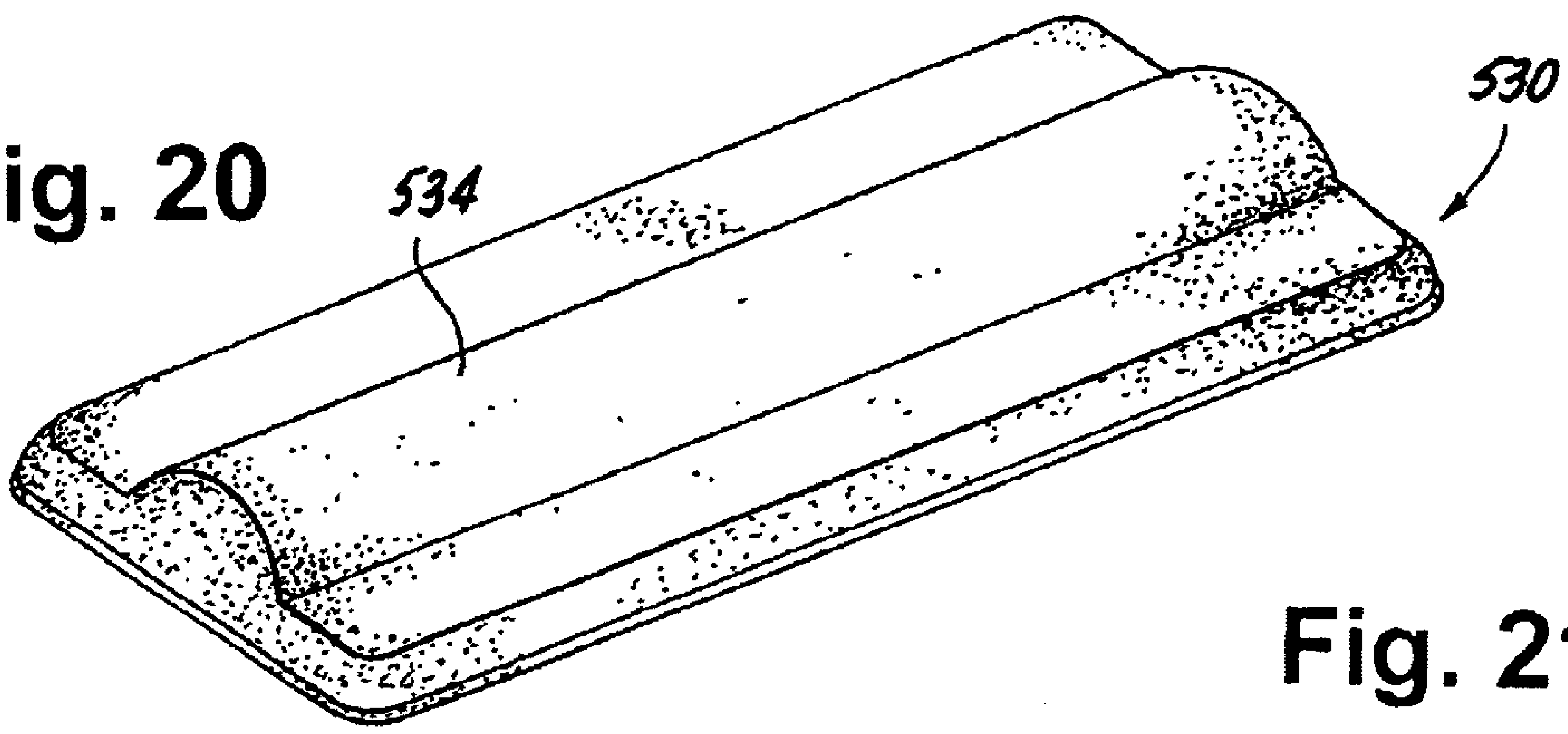
Fig. 20



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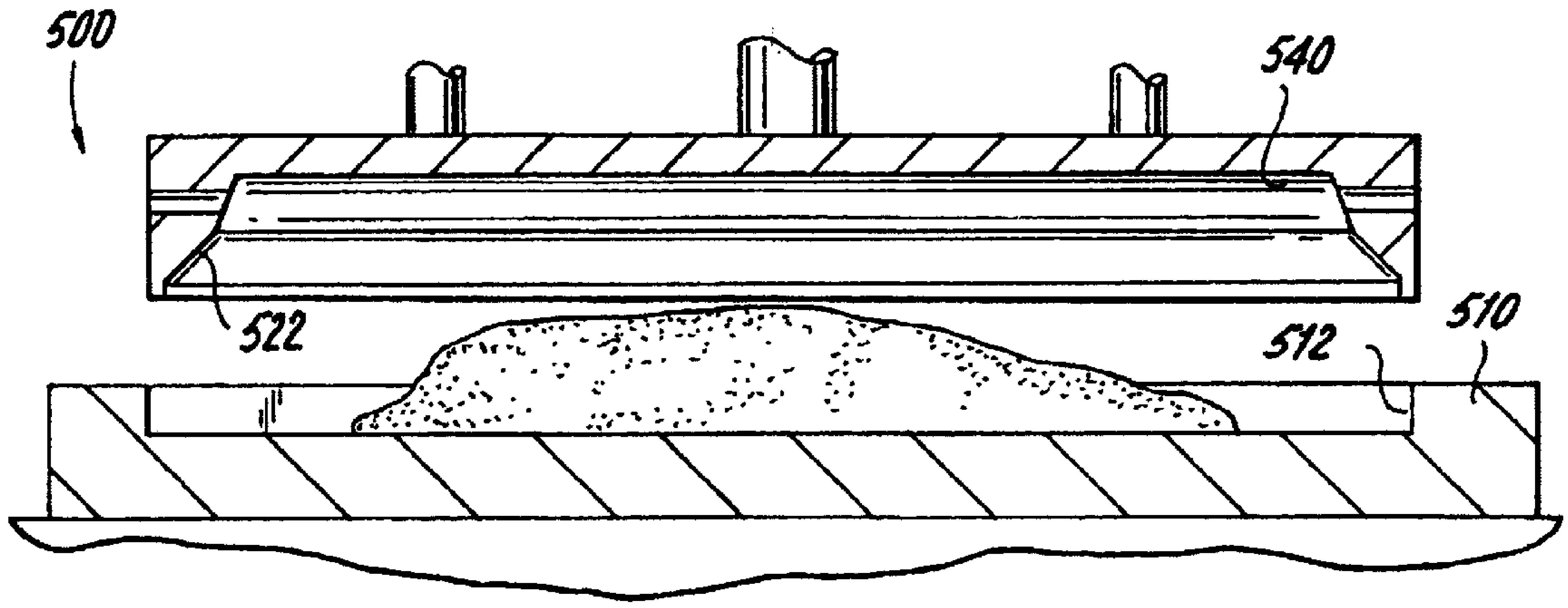

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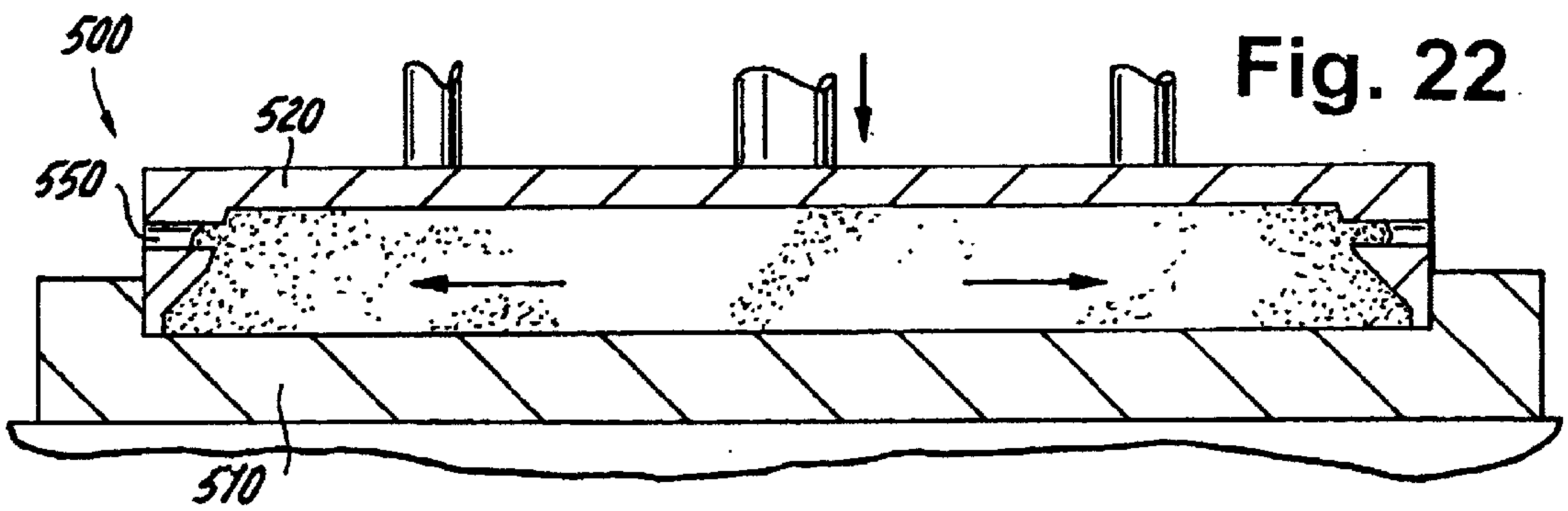

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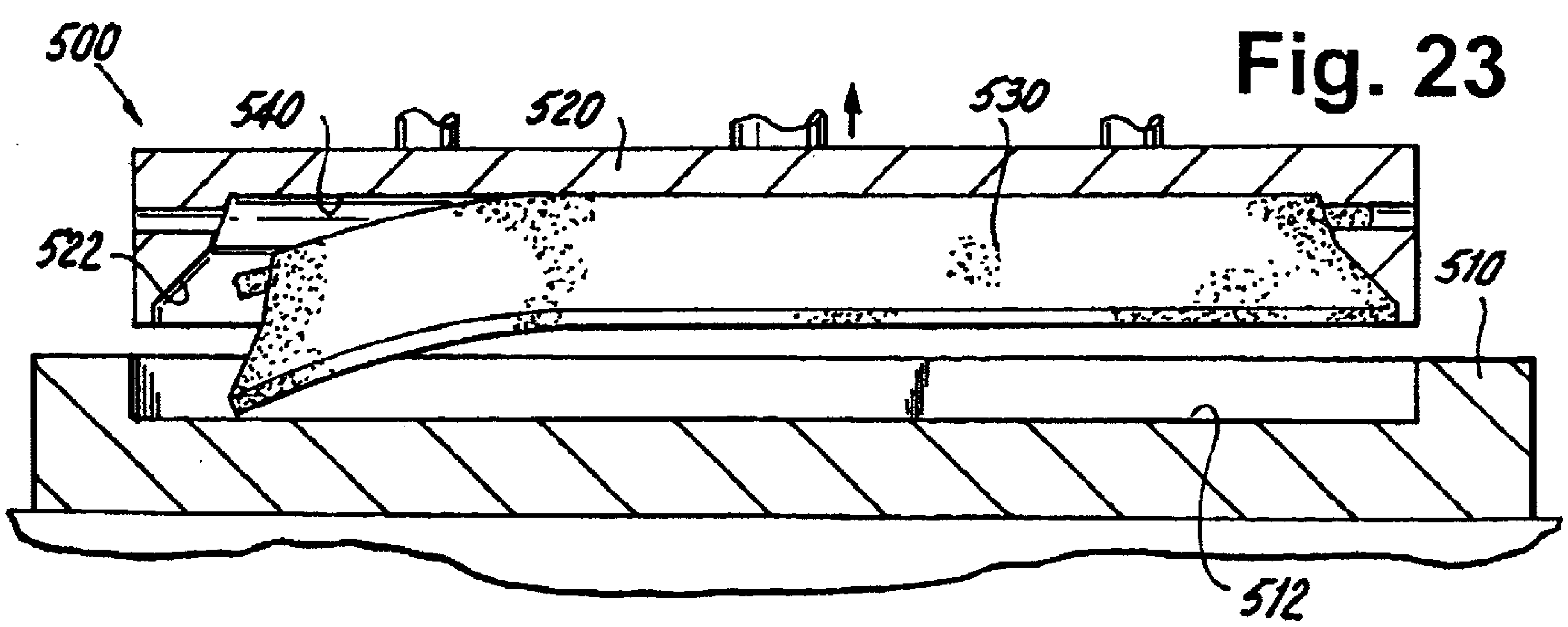

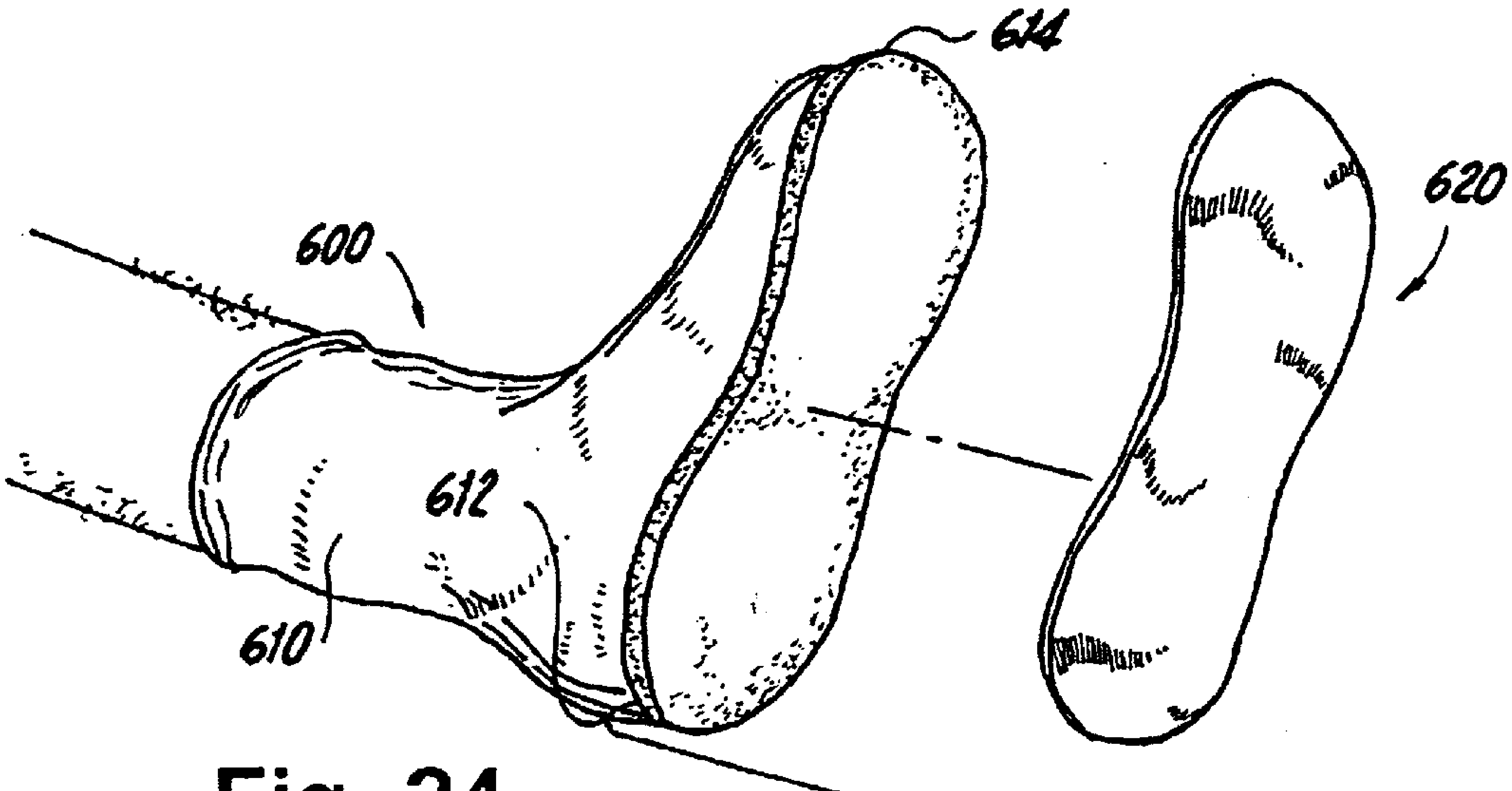
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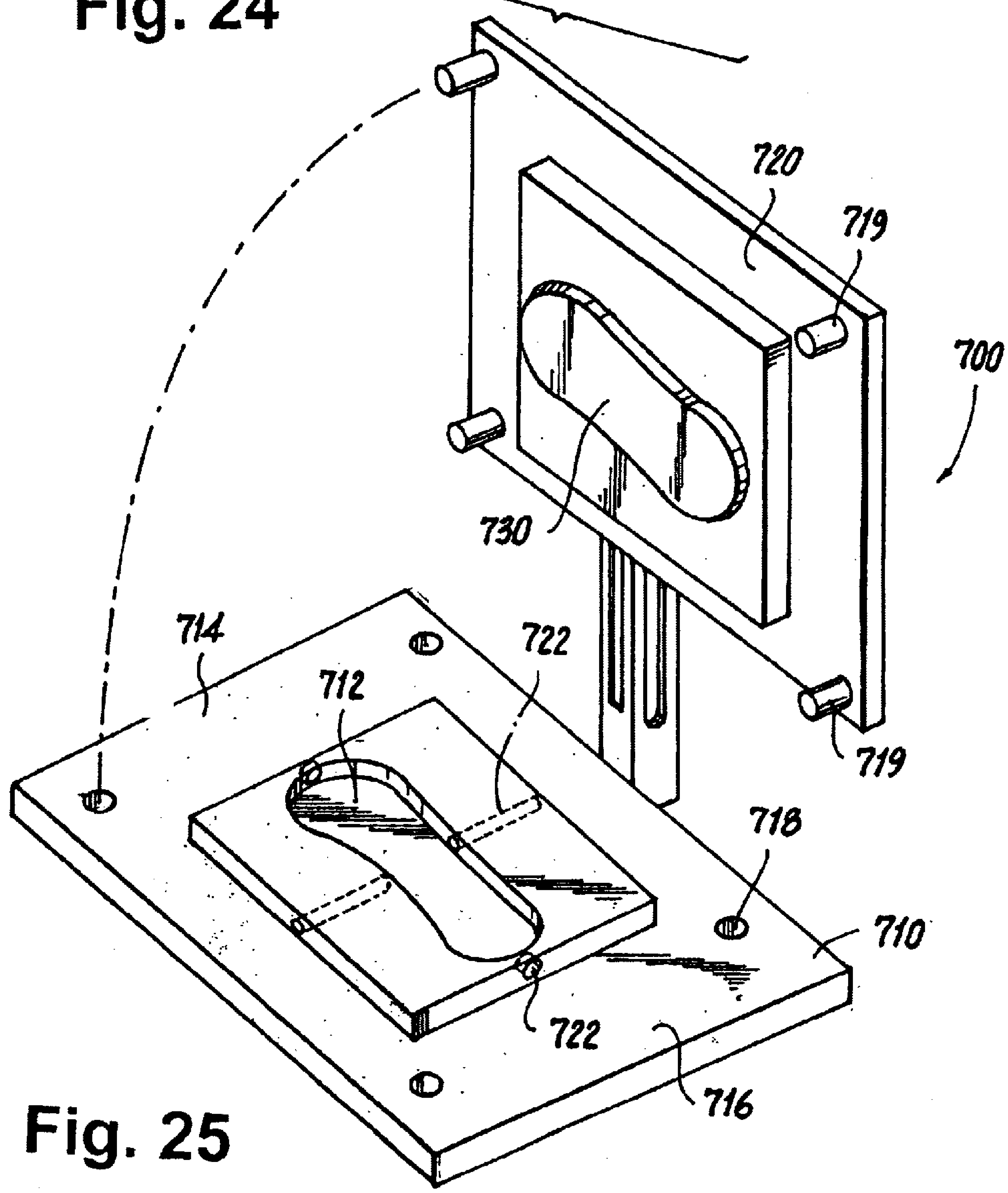
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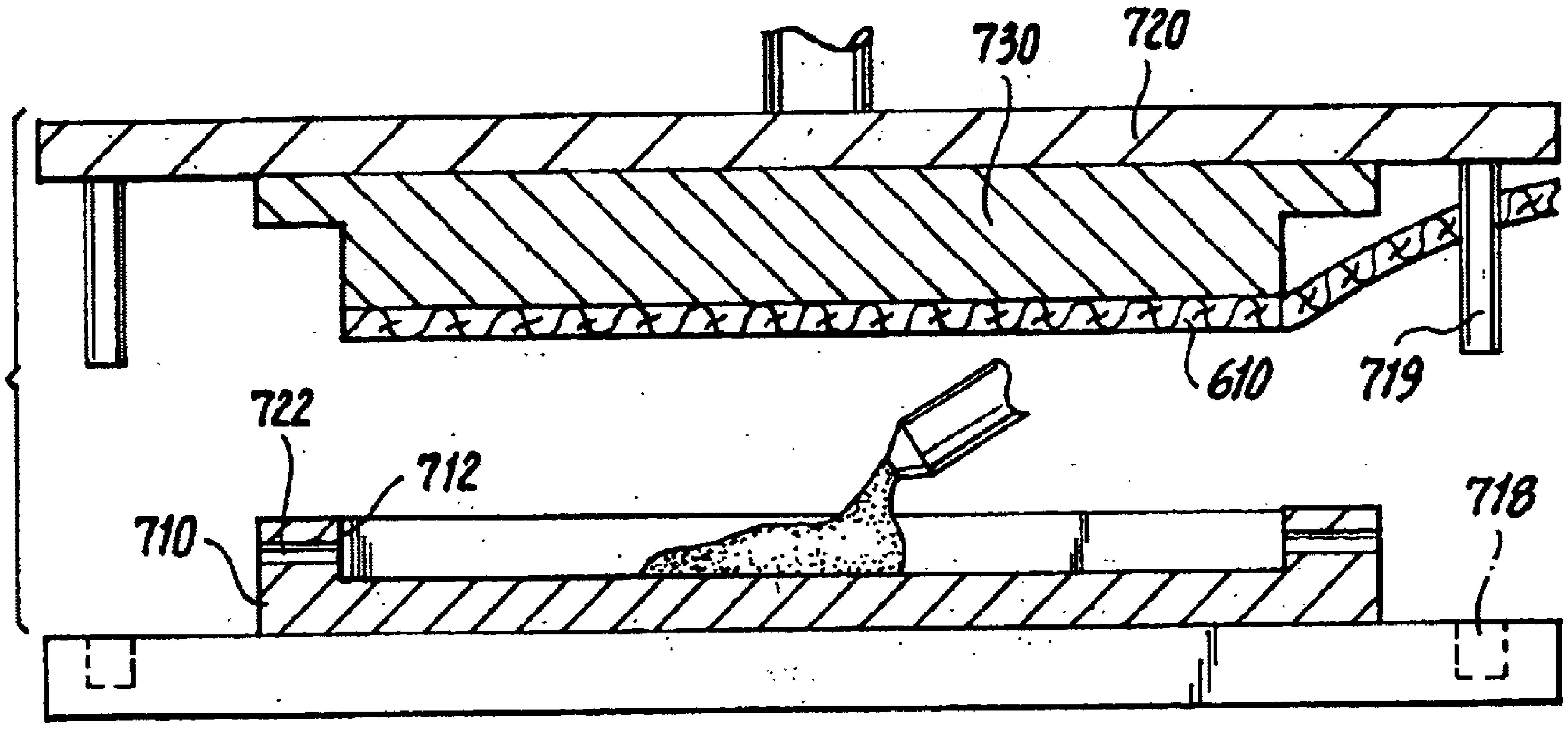
Fig. 25



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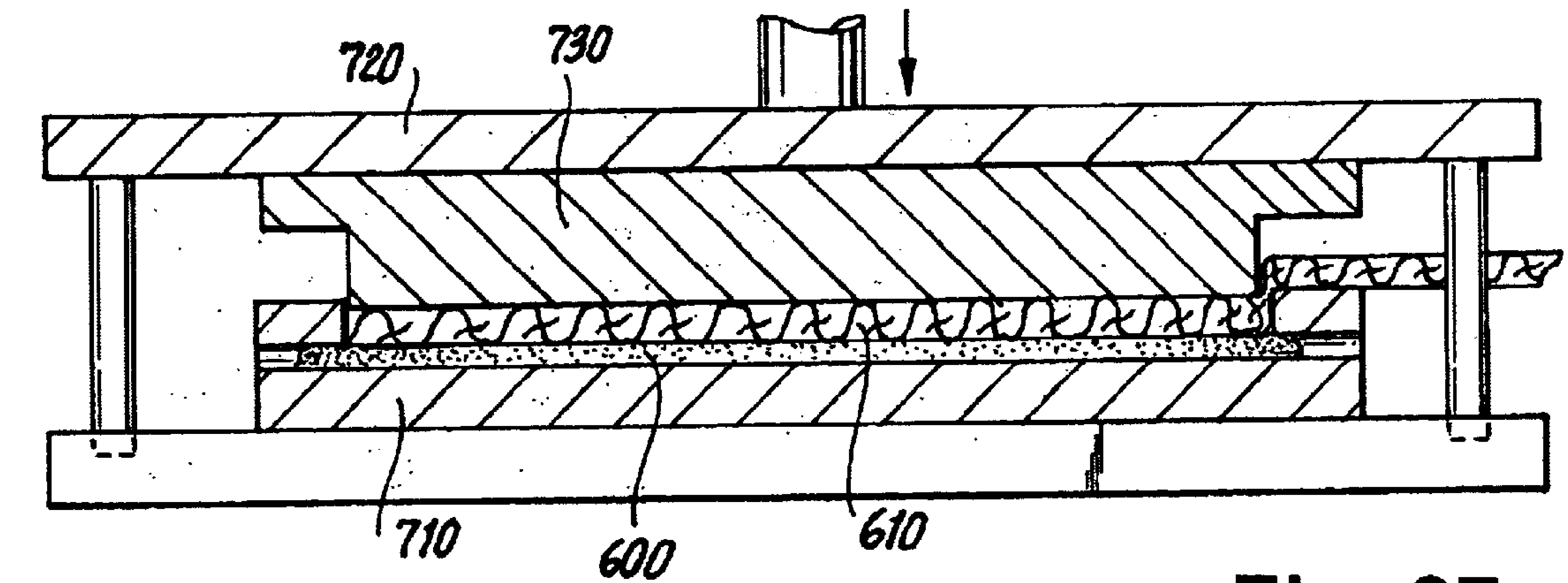

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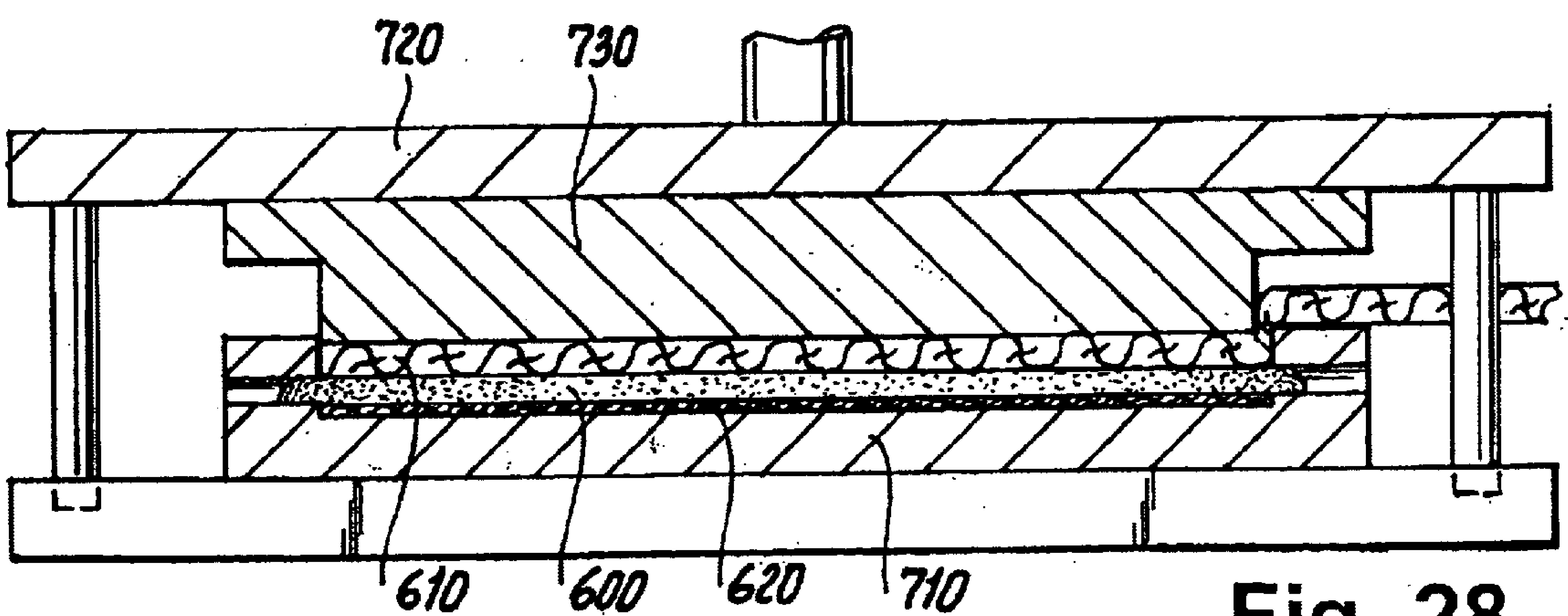

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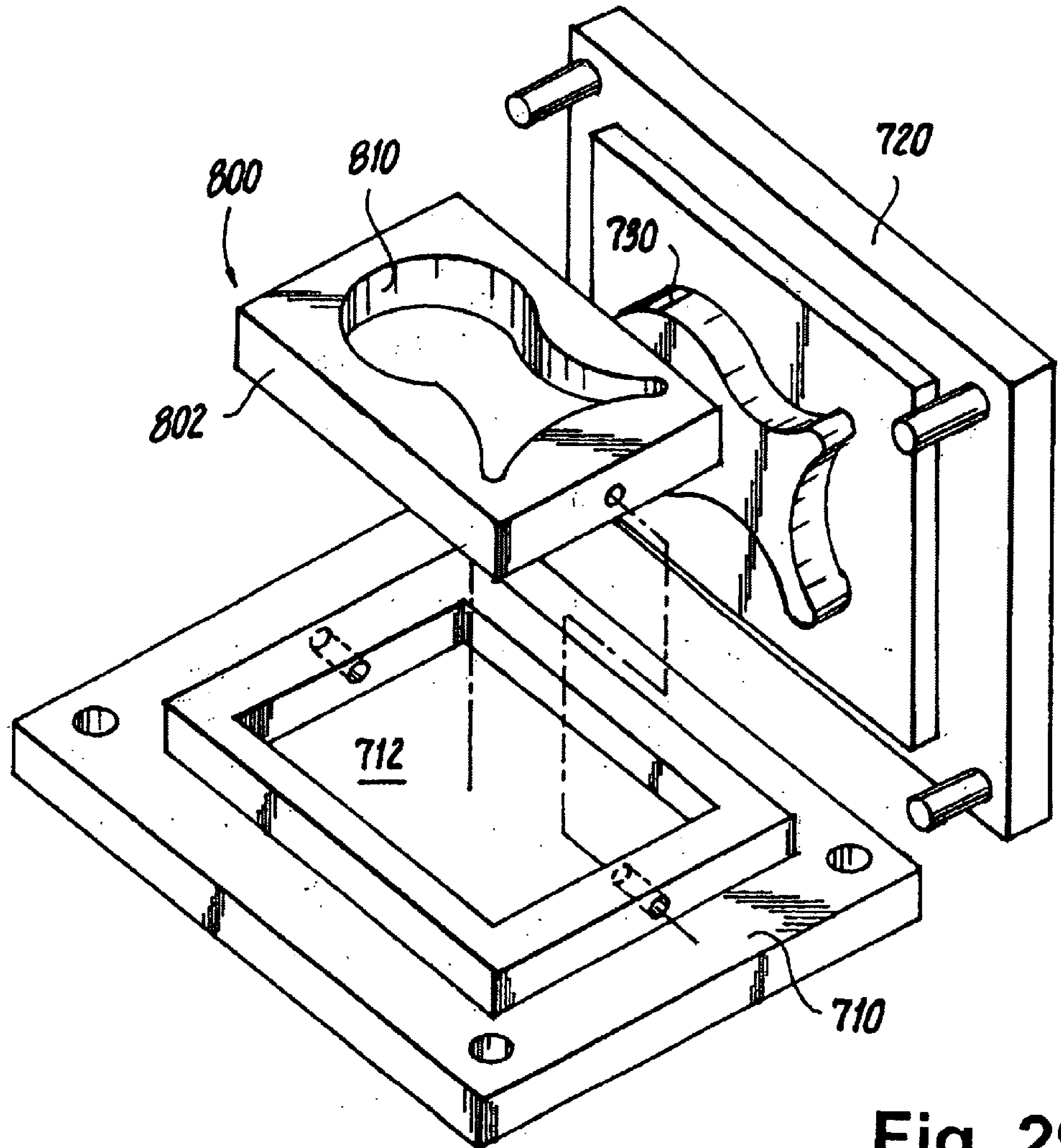

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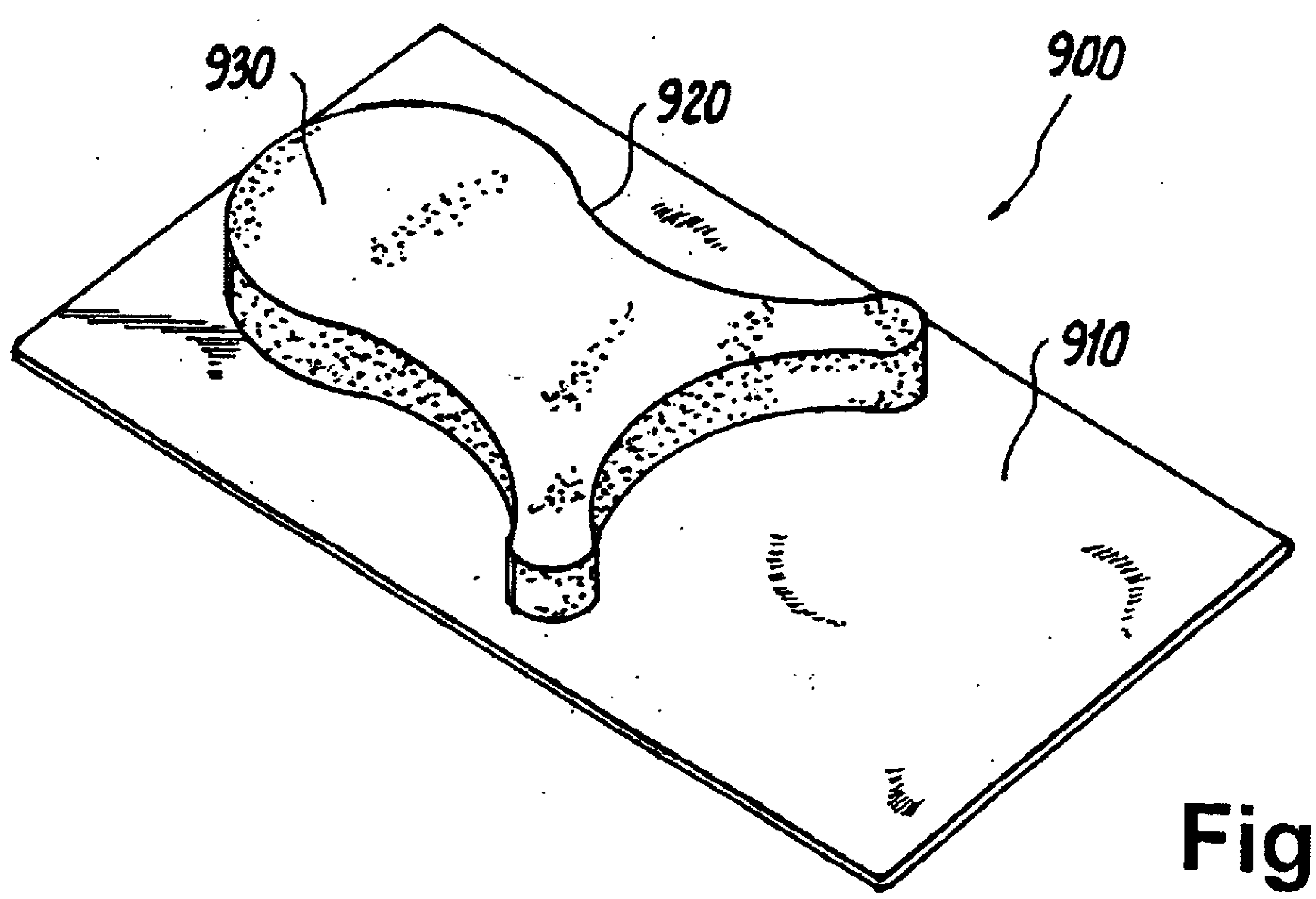

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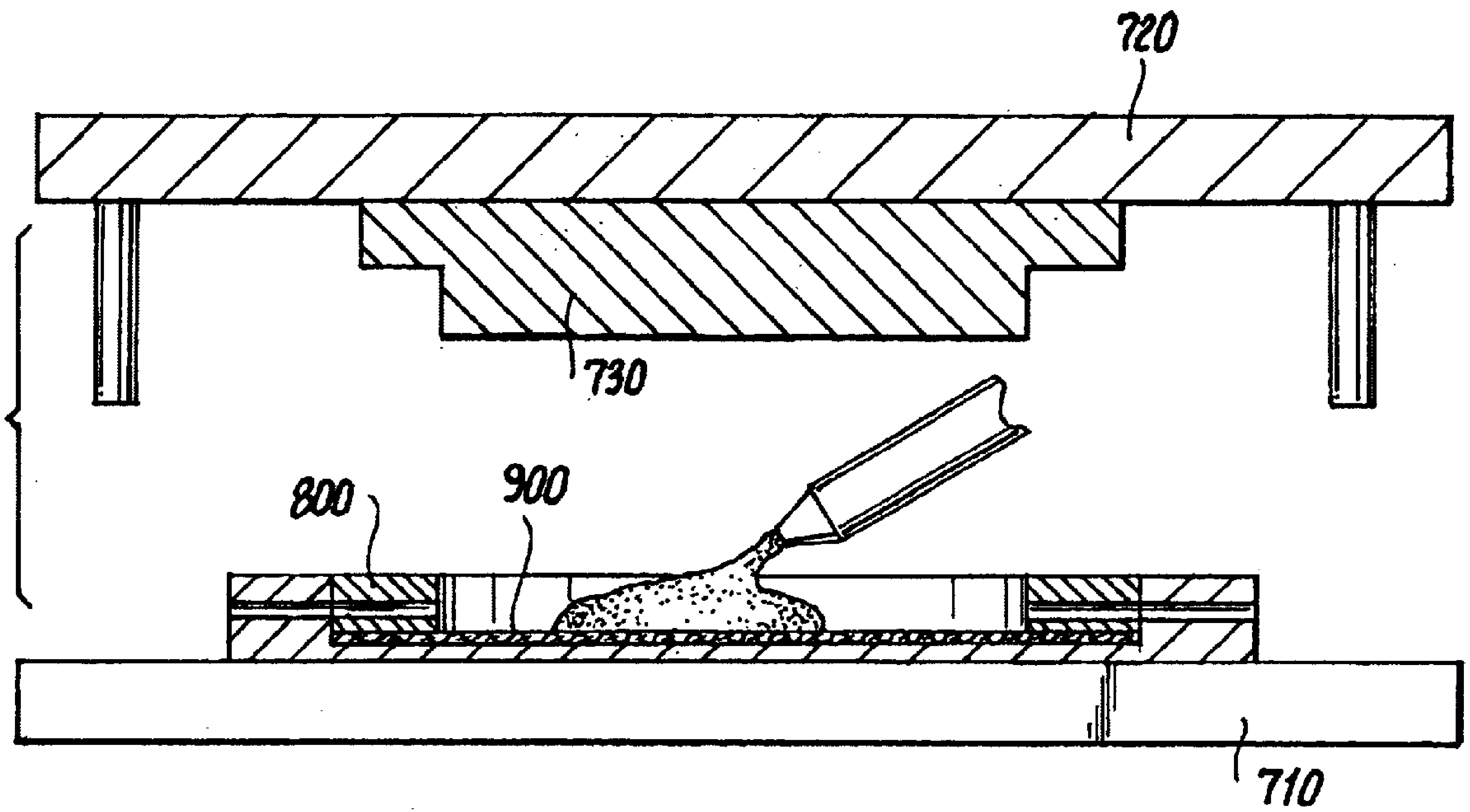

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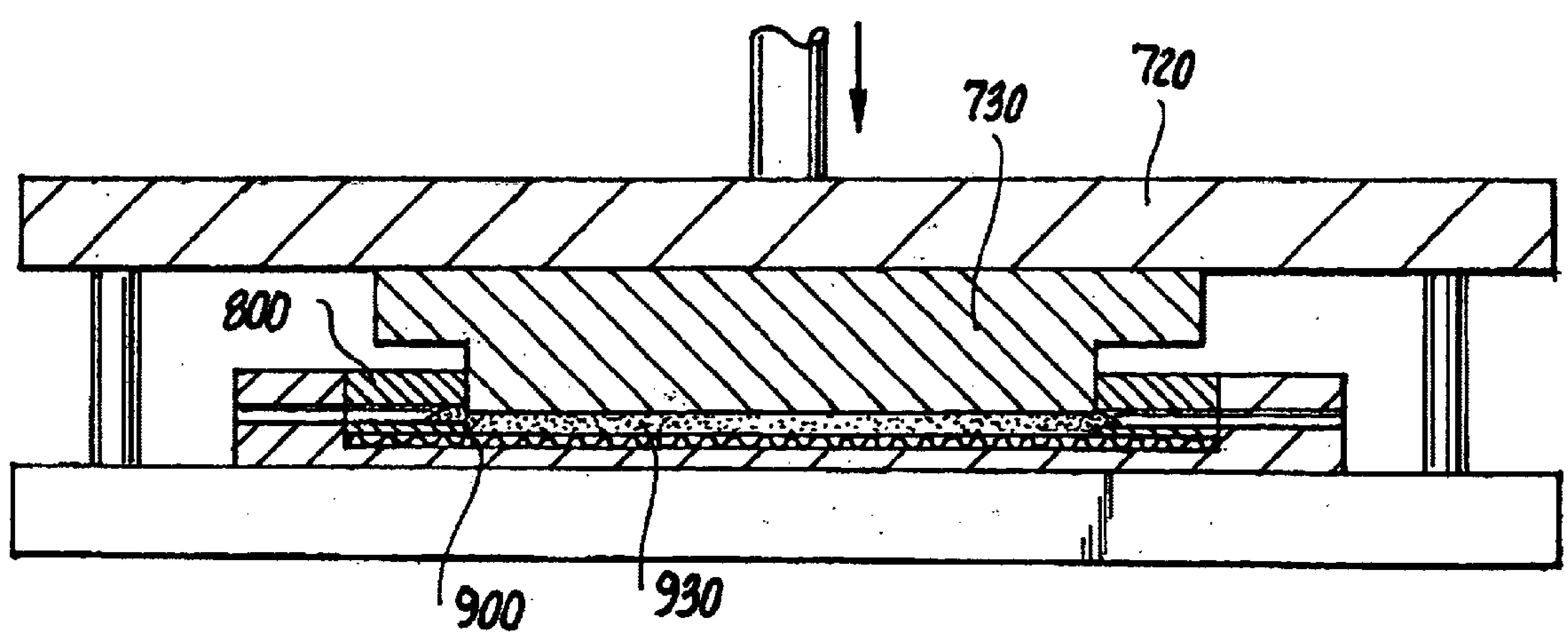

Fig. 32

PROCESS FOR APPLYING A CUSHION MATERIAL TO AN ARTICLE

TECHNICAL FIELD

The present invention relates generally to a process for forming a cushioned article having a predetermined thickness and contour and more particularly, to a process for applying a gel-like cushioning material to an inside of a liner body to form a cushioned liner that is constructed to be worn over an amputee's residual limb.

BACKGROUND

For the past decades, amputees have worn tubular sock-like articles over their residual limbs to provide additional comfort to the amputee when wearing a prosthetic limb. For many years, the tubular sock-like articles were formed of natural materials, such as cotton, wool, and cotton-wool blends; however, as synthetic materials become increasingly popular as a material of choice to form articles of apparel, including socks, the tubular sock-like articles were increasingly fabricated using synthetic materials.

As is known, an amputee is typically fitted with a prosthetic member to be worn on the residual limb. In a below-knee (BK) prosthesis, an amputee's stump tends to pivot within a socket of the prosthesis. During ambulation, the stump will come up in the socket of the prosthesis until the means for attaching the prosthetic to the wearer causes the prosthetic to lift with the stump. The wearer then completes a walking motion or other movement by repeatedly lifting the prosthetic up and then placing it back down in a different location to effectuate movement of the wearer's body.

Most of the available cushioned residuum socks (prosthetic liners) that are currently available have a tubular or conical construction and do not provide a form fit of the amputee's residuum since the residuum stump typically does not contain a completely uniform shape. For example, while the residuum stump generally has a roughly conical shape, the residuum stump will often have recessed areas in certain locations. On a below knee, left side residual limb, the recessed area is often more pronounced on the right side of the tibia bone, while for right side residual limbs, the more pronounced recessed area is on the left side of the bone. In both instances, the side opposite the side with the more pronounced recessed area will also contain a recessed area to a lesser degree and further the greatest recess typically occurs immediately below the patella, one either side. Conventional prosthetic liners do not accommodate the non-uniform nature of the residuum and this can result in the amputee experiencing wearing discomfort due to the non-uniform fit.

When the amputee uses a prosthetic device, the amputee simply attaches a prosthetic limb to their residual limb by means of a rigid socket, liner, and a suspension means. The rigid socket can be custom fabricated to match the shape of the intended user's residual limb and can be formed from a variety of different materials, including but not limited to thermoplastic materials, fiber-reinforced thermoset materials, as well as wood and metals. Because the residual limb interfaces with the hard, rigid prosthetic limb, this interface can become an area of discomfort over time since this interface is a load bearing interface between the residual limb and the prosthetic limb. In order to alleviate this discomfort and provide a degree of cushioning to lessen the impact of the load, prosthetic liners (socks) are used as interface members between the hard prosthetic socket and the residual limb in order to increase comfort.

Traditionally, several methods have been used to apply a cushion material to an article, such as a sleeve member intended for use as a prosthetic liner for placement over a residual limb. One process uses conventional dipping techniques in which the closed distal end of the sleeve member is dipped into cushioning material which exists in a liquid or molten state. The sleeve member is dipped into the cushioning material at a prescribed angle relative to the surface of the molten or liquified cushioning material so that the cushioning material extends up the sleeve member from the closed distal end to a further extent on the side of the sleeve member. The sleeve member is then manipulated in the liquified or molten cushioning material to effectively coat the surface of the sleeve member with the cushioning material. When the cushioning material is applied in this manner, the sleeve member has likely been inverted so that the interior surface is actually the exterior surface that is exposed to the liquified or molten cushioning material. After application of the cushioning material by dipping the inverted sleeve member into the liquified or molten cushioning material and permitting the cushioning material to sufficiently cool, the coated sleeve member is then inverted again so that the surface that has the cushioning material applied thereon becomes the interior surface of the cushioned sleeve member.

Prior to inserting (i.e., dipping) the sleeve member into the liquified or molten cushioning material, a mandrel or the like is inserted into the inverted sleeve member to stretch and shape the sleeve member to its intended tubular shape. The mandrel is thus a tool that permits a person to dip the sleeve member into the liquified or molten cushioning material without exposing the person to any unnecessary risks. The mandrel is then manipulated so that the exposed surfaces of the sleeve member are in contact with the cushioning material. In order to increase the thickness, the sleeve member is repeatedly dipped so as to effectively build-up the thickness of the cushioning material.

One of the disadvantages of the dipping process is that control of the thickness of the cushioning material is rather an arduous task and is fairly imprecise due to the thickness being built-up to a desired thickness by repeatedly dipping the sleeve member into the coating. Further, the sleeve member must be inverted before and after the cushioning material is applied to the sleeve member. After the cushioning material has been applied and allowed to cool, the final inversion of the cushioned sleeve member can cause crazing, folding or other imperfections to form in the layer of the cushioning material.

In addition to the application of the cushioning material to the sleeve member by dipping the sleeve member into liquified or molten cushioning material, the cushioning material can be "painted" onto the sleeve member or it is also possible to dissolve the polymeric material in a solvent followed by application of the solvent to the sleeve member with subsequent evaporation of the solvent, thereby leaving a layer of cushioning material formed on the sleeve member. This process is also marked by a degree of imprecision with respect to forming the cushioning material to a desired thickness.

Another process for applying a cushioning materials is an "open pour" process in which the cushioning material is poured into a mold and settles therein due to gravitational forces. This process does not involve compression of the material and is marked by the following disadvantages: it is difficult to precisely control the thickness and a poor bond typically results between the fabric and the material.

Further, all of the above-methods do not permit the thickness of the cushion layer to be specially contoured in select regions of the article for purpose of providing more or less comfort and protection in these regions.

Thus, there is still a need in the art for a simple yet effective process for applying a layer of cushioning material to a surface of an article, whereby the thickness of the cushion layer can be controlled to a high degree of precision and the profile of the cushion layer can also be controlled and varied depending upon the application.

SUMMARY

A number of different methods for applying a layer of cushioning material to a surface of an article are provided, whereby the thickness of the cushion layer can be controlled to a high degree of precision and the profile of the cushion layer can also be controlled and varied depending upon the application. In one exemplary embodiment, a process for forming a cushion layer of a preselected thickness on an inside of prosthetic liner body is provided. The process includes the steps of: (a) providing an apparatus including a mold having a cavity formed therein and a mandrel that is positionable between a retracted position and an extended position, wherein in the extended position, at least a portion of the mandrel is received within the cavity; (b) disposing the prosthetic liner body into the mold cavity; (c) disposing a quantity of cushioning material into the inside of the prosthetic liner such that the cushioning material pools at a distal end of the prosthetic liner, the quantity being a sufficient quantity to form the cushion layer of the preselected thickness; (d) directing the mandrel into the inside of the prosthetic liner until the mandrel is positioned in the extended position, the driving action of the mandrel causing the cushioning material to be dispersed between the mandrel and the prosthetic liner, thereby forming the cushioning layer of the preselected thickness; (e) cooling the cushioning material to form a cushioned prosthetic liner; and (f) withdrawing the mandrel from the mold cavity such that the cushioned prosthetic liner can be removed therefrom.

The present process is not limited to producing cushioned prosthetic liner; but rather can be used produce a number of different products, including but not limited cushioning pads with or without a fabric backing layer; cushioned elbow pads, cushioned socks, etc.

Because the distance between the mandrel and the prosthetic liner (or cavity wall in other embodiments) corresponds to the thickness of the cushioned article to be formed, the present process permits the thickness of the cushion layer to be controlled with enhanced precision since this distance between the mandrel and the prosthetic liner (or cavity wall) along its length is readily determinable and know and therefore, the precise thickness is readily controllable. The above process also permits the profile (contour) of the cushion layer to be readily changed by altering a surface of one of the mandrel and the cavity.

Other features and advantages of the present invention will be apparent from the following detailed description when read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other features of the present invention will be more readily apparent from the following detailed description and drawings of illustrative embodiments of the invention in which:

FIG. **1** is a perspective view of a cushioned prosthetic liner according to one exemplary embodiment being placed on a residual limb of an amputee;

FIG. **2** is a perspective view of the prosthetic liner of FIG. **1** with the residual limb being fully inserted into the prosthetic liner;

FIG. **3** is a partially exploded perspective view of the prosthetic liner of FIG. **1** with a section of the prosthetic liner being shown in cross-section;

FIG. **4** is an exploded perspective view of a sleeve member of the prosthetic liner illustrating exemplary points of attachment between the individual components;

FIG. **5** is a perspective an exemplary fabric taken from circle **5** of FIG. **4** used to form the individual components of the sleeve member of FIG. **4**;

FIG. **6** is a cross-sectional view taken from circle **6** of FIG. **3**;

FIG. **7** is a side elevational view, in partial cross-section, of an apparatus for applying a cushioning material to a liner body to form the cushioned liner of FIG. **1**;

FIG. **8** is an enlarged cross-sectional view illustrating a housing member having a cavity for receiving the liner body which in turn receives liquid or molten cushioning material;

FIG. **9** is a side elevational view, in partial cross-section, of the apparatus of FIG. **7** illustrating a mandrel being extended to an intermediate position inside of the liner body;

FIG. **10** is a side elevation view, in partial cross-section, of the apparatus of FIG. **9** illustrating the mandrel being further extended to a distal position;

FIG. **11** is an enlarged cross-sectional view of the mandrel in the distal position of FIG. **10** with cushioning material flowing around the mandrel between the mandrel and the inside surface of the liner body;

FIG. **12** is a side elevational view of the apparatus of FIG. **7** illustrating the mandrel being retracted from the cavity with the cushioned liner of FIG. **1** surrounding the mandrel;

FIG. **13** is a side elevation view of the mandrel in the retracted position of FIG. **12** with the cushioned liner being rolled or peeled therefrom for removal of the cushioned liner;

FIG. **14** is side elevational view of an apparatus according to an alternative embodiment for applying a cushioning material to a liner body to form the cushioned liner of FIG. **1**, wherein the mandrel is formed to have a non-uniform shape;

FIG. **15** is an enlarged cross-sectional view illustrating the mandrel of FIG. **14** being inserted into a liner to form a cushion layer having a section of increased thickness;

FIG. **16** is a perspective view of a cushioned article;

FIG. **17** is a cross-sectional side elevational view of an exemplary apparatus for forming the article of FIG. **16** with a mandrel being shown in the retracted position;

FIG. **18** is cross-sectional side elevational view of the apparatus of FIG. **17** with the mandrel being in the fully extended position;

FIG. **19** is a cross-sectional side elevational view of the apparatus of FIG. **17** with the mandrel being retracted to permit removal of the article;

FIG. **20** is a perspective view of an alternative cushioned article having a surface feature;

FIG. **21** is a cross-sectional side elevational view of an exemplary apparatus for forming the article of FIG. **20** with a mandrel being shown in the retracted position;

FIG. 22 is cross-sectional side elevational view of the apparatus of FIG. 21 with the mandrel being in the fully extended position;

FIG. 23 is a cross-sectional side elevational view of the apparatus of FIG. 21 with the mandrel being retracted to permit removal of the article;

FIG. 24 is a perspective of a cushioned sock article with an optionable liner being exploded therefrom;

FIG. 25 is a perspective view of an exemplary apparatus for forming the sock article of FIG. 24;

FIG. 26 is a cross-sectional side elevational view of the apparatus of FIG. 25 with a mandrel being in a retracted position with the sock arranged thereabout and the cushioning material being injected into a mold cavity;

FIG. 27 is cross-sectional side elevational view of the apparatus of FIG. 26 with the mandrel in the fully extended position;

FIG. 28 is a cross-sectional side elevational view of the apparatus of FIG. 26 with the liner being disposed in the mold cavity and the mandrel being in the fully extended position;

FIG. 29 is a perspective view of the apparatus of FIG. 25 with a cast member being shown;

FIG. 30 is a perspective view of another article formed by the apparatus of FIG. 29;

FIG. 31 is a cross-sectional side elevational view of the apparatus of FIG. 29 with the mandrel in the retracted position; and

FIG. 32 is a cross-sectional side elevational view of the apparatus of FIG. 29 with the mandrel in the fully extended position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to FIGS. **1** through **6**, a cushioned liner (e.g., a prosthetic liner) **100** according to one exemplary embodiment is illustrated. The cushioned liner **100** is formed of a liner body **110** having a form fitting generally tubular shape with an open end **112** into which an amputation stump (residual limb) **130** can be introduced and a closed distal end **114**. The liner body **110** includes an interior **116** and an exterior **118** with the interior **116** being impregnated with a cushioning material to form a cushion layer **120** so as to provide a cushion between the amputee's residual limb **130** and a prosthetic device (not shown) which is to be attached to or otherwise coupled to the residual limb **130**, as will be described in greater detail below.

When the cushioned liner **100** is used to couple a prosthetic device to the residual limb **130**, a pin receptacle **150** is preferably provided and is attached to the distal end **114** of the cushioned liner **100** on the exterior **118** thereof. In the exemplary embodiment, the pin receptacle **150** has a resilient radial skirt portion **152** surrounding a receptacle body **154**. The receptacle body **154** is a rigid member that is preferably formed of metal and includes a threaded bore **156** which threadingly receives a connecting member (e.g., a threaded pin) of the prosthetic device to securely attach the prosthetic device to the cushioned liner **100**. The radial skirt portion **152** preferably has a diameter that is approximately equal to or less than the diameter of the distal closed end **114** of the liner body **110** so that the radial skirt portion **152** does not extend beyond the peripheral edge of the liner body **110** at the distal end **114** thereof. In other words, there should be a smooth radial interface between the radial skirt portion **152** and the liner body **110**. However, in some applications, it may be desirable for the radial skirt portion **152** to extend beyond the peripheral edge of the liner body **110**.

The radial skirt portion **152** is a flexible member that is formed of a resilient material, such as a polymeric material. The receptacle body **154** can be formed of any number of materials, such as metals, and in one embodiment, the receptacle body **154** is formed of aluminum.

The pin receptacle **150** is disposed at the closed distal end **114** of the liner body **110** using any number of techniques. When the pin receptacle **150** is disposed on the distal end **114**, the receptacle body **154** is generally centered about the distal end **114**. The receptacle body **154** has an annular base **155** (i.e., radial flange) that surrounds an annular boss **157** that includes the threaded bore **156**. Preferably, the radial skirt portion **152** is formed over the receptacle body **154** and the polymeric material forming the radial skirt portion **152** surrounds the outer surface of the annular boss **157**. In other words, the only portion of the receptacle body **154** that is exposed is the threaded bore **156** to receive the connecting member of the prosthetic device and establish a connection between the cushioned liner **100** and the prosthetic device.

Suitable techniques for attaching the pin receptacle **150** to the closed distal end **114** include but are not limited to using an adhesive material to bond the pin receptacle **150** to the textile material of the closed distal end **114**. It will also be appreciated that a molding process can be used to form the radial skirt portion **152** around the receptacle body **154** and at the same time bond the socket **150** to the distal end **114** of the cushioned sleeve member **100**. For example, the receptacle body **154** can be placed into a mold, along with the distal end **114** of the liner body **110** and then polymeric material can be introduced into a mold cavity, thereby forming the radial skirt portion **152** and attaching the pin receptacle **150** to the cushioned liner body **110**.

As best shown in the exploded view of FIG. **4**, one exemplary liner body **110** is formed of several or more pieces (panels) of textile material that are cut according to an exemplary pattern and then attached to one another along predetermined seams to provide the constructed liner body **110**. In one exemplary embodiment, the liner body **110** is formed of three pieces of textile material, namely first and second side panels **160**, **170** and a distal panel **180**. Preferably, the first and second side panels **160**, **170** are identical to one another. Each of the first and second side panels **160**, **170** has an upper edge **162** that forms the open end **112** of the liner body **110** when the first and second side panels **160**,**170** are attached and an opposing lower edge **164** that forms the closed distal end **114** of the liner body **110**.

When each of the first and second side panels **160**, **170** is flattened out, each panel has a generally rectangular shape with a slight inward taper toward the lower edge **164**. In other words, the upper edge **162** has a width slightly greater than the width of the lower edge **164**. Each of the first and second side panels **160**, **170** has an interior surface **172** (that forms a part of the interior **116** of the liner body **110**) and an opposing exterior surface **174** (that forms a part of the exterior **118** of the liner body **110**). As best shown in FIG. **4**, the first and second side panels **160**, **170** are attached to one another along side edges **166** of each. The side edges **166** extend from the lower edge **164** to the upper edge **162**.

The distal panel **180** is a textile piece that is cut to have an annular shape or some other desired shape so long as the distal panel **180** encloses one end of the liner body **110** when it is connected to the side panels **160**, **170**. The distal panel **180** has an interior surface **182**, an exterior surface **184** and a peripheral, circumferential edge **186**. The dimensions of the distal panel **180** should be such that when the first and second side panels **160, 170** are attached to one another, the distal panel **180** completely extends across the open lower edge (i.e., defined by the lower edges **162** of the panels **160, 170**) so as to enclose the distal end (second end **114**) of the liner body **110**. Accordingly when the first and second side panels **160, 170** are attached to one another along the side edges **166** to form vertical seams, the liner body **110** has a tubular shape and the distal panel **180** is used to enclose the liner body **110**. The distal panel **180** is attached to the lower edges **162** of the first and second side panels **160, 170** along its peripheral, circumferential edge **186**.

As best shown in FIG. **5**, the interior surfaces **172, 182** of the first and second side panels **160, 170** and the distal piece **180**, respectively, have a different texture than the exterior surfaces **174, 184**. As will be described in greater detail hereinafter, the textile panels **160, 170, 180** are preferably formed of two different materials that are knit together so that the fibers of one material form the exterior surface of the respective piece and the fibers of the other material form the interior surface of the respective piece. The texture of the interior surfaces **172, 182** is designed to absorb the cushioning material that is applied to the interior surfaces **172, 182** to form the cushion layer **120**, while not permitting the cushioning material to bleed through or otherwise migrate to the exterior surfaces **174, 184** thereof. As illustrated in FIG. **5**, the exemplary interior surface of the textile material has a waffle-like appearance for absorbing the cushioning material.

Referring now to FIGS. **1** through **8**, the two side panels of material **160, 170** used to construct the liner body **110** can be attached to one another using any number of conventional techniques, including stitching the two side panels **160, 170** of textile material along the side edges **166** to form vertical stitched seams **171**. When the two side panels **160, 170** are stitched to each other, a wide variety of thread types can be used and a number of different stitch types can be used. In one exemplary embodiment, thread formed of a synthetic material, such as nylon, is used to attach the two side panels **160, 170** to one another using a flat-locked stitch. A flat-locked stitch is preferred because this type of stitch tends to create a smooth seam that is less irritating than seams formed of other stitches. A flat-locked stitch also permits the two side panels **160, 170** to sufficiently stretch to accommodate the stretching of the cushioned liner **100** that occurs during the normal wear of the cushioned liner **100**.

Similarly, the distal panel **180** of textile material can be connected to the distal lower ends **164** of the two side panels **160, 170** along a circumferential stitched seam **173** using any number of stitch types. However, the distal panel **180** of material is preferably connected to the distal lower ends **164** of the first and second side panels **160, 170** of material using a circumferential seam **173** that has a flat-locked stitch.

The first and second side panels of material **160, 170** and the distal panel **180** can be formed of any number of different textile materials having a predetermined thickness (ply). Preferred textile materials are textile fabrics that have an elasticity that permits the prosthetic liner (cushioned liner **100**) to stretch a predetermined amount during normal application of the cushioned liner **100** to the residual limb **130** and during the normal motions of the cushioned liner **100** as the wearer takes steps or otherwise moves the prosthetic limb (i.e., the prosthetic device). For example, the two side panels **160, 170** and the distal panel **180** can be formed of fabrics selected from the group consisting of: stretchable non-woven fabrics (e.g., the Xymide line of fabrics including Wearforce® fabrics from DuPont,

Wilmington, Del.); Lycra® based materials which include segmented elastomeric polyurethane fibers (i.e., spandex type fabrics); supplex nylon, neoprene fabrics (polychloroprene fabrics); nylon, spunbonded olefin; looped nylon; spunlaced fabrics; polyester; polypropylene; and aramid fiber fabrics. It will be appreciated that the above list of suitable fabric materials is not exhaustive and is merely exemplary in nature and not limiting of the types of fabric materials that be used to form the liner body **110**. Further, it will be appreciated that the fabrics used to form the present liner body **110** are preferably elastic fabrics that can be provided in a woven, knitted, or non-woven form.

One preferred fabric material that is used to form the two side panels **160, 170** and the distal panel **180** is a fabric formed of polyester and polypropylene knit fibers. As shown in FIG. **5**, the fabric is constructed (knit) in such a way that the polyester fibers form one surface of the fabric and the polypropylene fibers form the opposite surface of the fabric. In the present prosthetic liner, the polyester surface is intended to form a part of the exterior **118** of the liner body **110**, while the polypropylene surface is intended to form a part of the interior **116** of the liner body **110**. The polypropylene surface has a distinct texture in that it has a waffle-like texture. When the fibers are knitted in this manner (waffle-like), a number of interstices are formed across the polypropylene surface. As will be described in greater detail hereinafter, the interstitial characteristic of the side of the fabric that forms the interior of liner body **110** advantageously permits gel that is applied to the interior of the liner body **110** to be readily absorbed within the interstices. This type of fabric is commercially available from Milliken & Company of Spartanburg, S.C. under the style/pattern No. 952561-804. Advantageously, a fabric constructed in the aforementioned manner allows the cushioning material to enter into the denure of the fabric but is resistive to the cushioning material migrating through the fabric from the interior surface **116** across the exterior surface **118**. In the final product, the cushioning material should be confined to the interior surfaces **116**, while the exterior surfaces **118** are free from the cushioning material.

The material used to form the liner body **110** is preferably elastic (stretchable) in one or more, preferably two, directions and is capable of adjusting to variations in form and size of the residual limb **130**. Depending upon the precise application, the thickness of the textile material (e.g., fabric) can be altered and while in one embodiment, the material/material thickness of each of the first and second side panels **160, 170** is the same as the material/material thickness of the distal panel **180**, it will be appreciated that the material and/or material thickness of any one of the first and second side panels **160, 170** and the distal panel **180** can be different from the other pieces. In one exemplary embodiment, the thickness of the fabric material used to construct the liner body **110** is from about 0.010 inch to about 0.200 inch. In the embodiment where the fabric material is a knit of polyester and polypropylene fibers, the thickness of the fabric material is about 0.04 inch; however, the thickness of the polyester/polypropylene knit can vary depending upon the particular application.

As best shown in FIGS. **9** through **11**, the cushioned liner **100** of FIGS. **9** and **10** provides a number of advantages over conventional prosthetic liner. More specifically, the distal seam of the traditional prosthetic liner **10** has been eliminated by constructing the present cushioned liner **100** so that it includes a distal panel **180** at the distal end **114** that is attached to the two side fabric panels **160, 170** along the circumferential seam **173** that extends around the peripheral edge of the distal panel **180** instead of being formed across a medial section as in the traditional prosthetic liner **10**. By eliminating a distal seam that extends across the distal end of the prosthetic liner, such as a conventional distal seam the wearer of the present cushioned liner **100** experiences increased comfort since the conventional distal seam is associated with irritation and general discomfort, even in the cases when the conventional distal seam is covered with a cushioning material.

It will be appreciated that the distal end **114** of the cushioned liner **100** does not include a seam that is positioned in a location where the residual limb **130** will come into contact therewith. In many cases, the residual limb **130** tapers inwardly toward its distal stump end due to the natural shape of a leg and as a result of typical surgical techniques that are employed during an amputation procedure. The residual limb **130** thus rests against the cushion layer **120** in an area that is within the circumferential seam **173** or at least preferably contacts the circumferential seam **173** at the most peripheral portions of the residual limb **130**. At the very least, the wearer of the present cushioned liner **100** does not experience a distal seam running across underneath the residual limb **130** and preferably, the cushioned liner **100** is constructed so that the contact between the residual limb **130** and the circumferential seam **173** is negligible or nonexistent. As previously-mentioned, this distal end of the residual limb **130** is an extremely sensitive area and therefore, the elimination of any stitching across this sensitive area, provides a cushioned sleeve member that is substantially more comfortable than traditional prosthetic liners.

The cushioning material is applied to the interior surfaces **172, 182** of the first and second side panels **160, 170** and the distal panel **180**, respectively, to form the cushion layer **120**. The process of applying the cushioning material and controlling the thickness of the cushioning material, so as to permit contouring of the cushioning material, along the interior surface **116** of the liner body **110**, will be described in greater detail below. Preferably, the cushioning material is applied to interior surfaces **172** of the first and second side fabric panels **160, 170** to coat these panels from the lower edge **164** to the upper edge **162** and is also applied to the interior surface **182** of the distal panel **180**.

As previously-mentioned, the cushioned liner **100** includes the layer **120** of cushioning material and has a form fitting shape with an open end **112** into which the amputation stump **130** may be introduced, a closed end opposite the open end, an interior and an exterior. The interior of the cushioned liner **100** is defined by the interior surfaces **172, 182** of the panels **160, 170, 180** that are attached to one another and the interior surfaces **172, 182** are impregnated with a cushioning material to provide a cushion (e.g., cushion layer **120**) between the amputee's residuum **130** and any prosthetic device to be worn, attached to, etc., the residuum **130**.

The cushioning material is preferably a polymeric material and in one exemplary embodiment, the cushioning material is formed of a gel, a thermoplastic elastomer, or a combination thereof. For example, suitable thermoplastic elastomers include but are not limited to thermoplastic rubbers, silicon containing elastomers, thermoformable materials, etc., that provide a comfortable interface between the residuum **130** and a prosthetic device.

In one exemplary embodiment, the cushioning material is a polymeric gel that is composed of a block copolymer and mineral oil. The gel that can be used to form the cushioning material can either be a nonfoamed gel or a foamed gel (which is produced using a foaming agent). The mineral oil is present in an amount that is effective to produce a cushioning material having desired properties and is preferably present in from 0–85% by weight based on total weight, depending upon the precise application.

The polymeric material used to form the cushioned liner **100** is characterized by a certain durometer range. According to one exemplary embodiment, durometers for the cushioning material range from 1–20 on the Shore "A" scale. The lower the Shore A number, the softer the material, typically due to a higher level of plasticizer. Preferably the polymeric gel has a durometer (Shore A) that matches or approximates human skin and it has been found that the above durometer range of 1–20 generally provides the gel material with suitable characteristics. In one embodiment, the mineral oil is present on an equal weight basis, or in a weight ratio of 1/4, with regard to the amount of polymeric material present. The mineral oil is preferably purified mineral oil and is preferably USP grade.

In one exemplary embodiment, the cushioning material is formed of a Kraton®-type rubber material (Shell Chemical Co.). For example, the polymeric material can be formed of the following Kraton® rubbers: styrene-ethylene/butylene-styrene block copolymers or styrene-ethylene/propylene block copolymers and are available in triblock and diblock form.

The polymeric cushioning material can also be a blend of Kraton® rubbers and oils, such as mineral oils, (including typical stabilizers) which provide an average durometer of from 1–20. These blends typically are formed of a rubber having a lower durometer (1–10 of the Shore "A" scale) and a rubber having a higher durometer (e.g., 11–20). The blends are preferably capable of being stretched 100% or more before tearing and are capable of providing a form fit to the residual limb due to their inherent elasticity. Further, low durometer Kraton® rubbers and other materials tend to provide the cushioning material disposed of the interior **116** of the cushioned liner **100** with a sticky feeling which enhances the ability of the cushioned liner **100** to be form fitted against the residual limb **130** due to the intimate contact between the cushioning material and the skin.

In one exemplary embodiment, the polymeric material is a styrene isoprene/butadiene block copolymer or styreneethylene/butadiene-styrene block copolymer. Suitable polymeric materials, having the aforementioned desired properties, are commercially available from a number of sources. For example, polymeric materials commercially distributed under the trade names C-Flex 1970-W5 (R70–339–000), C-Flex 1960-W5 by Consolidated Polymer Technologies of Largo, Fla. and under the trade name Kraton G1654 by Shell Chemical Co. are suitable for use in producing the cushioning material.

The ratio of polymer to mineral oil will vary depending upon the precise application and upon the desired characteristics of the cushioned liner **100**. Generally, the ratio of polymer to mineral oil can be from about 1:1 to about 4:1. In addition to using styreneisoprene/butadiene or styrene-ethylene/butadiene-styrene block copolymers (mixed with mineral oil), other suitable polymeric materials include styrene-butadiene-styrene and any thermoplastic elastomer or thermoformable material that is capable of being blended with mineral oil and can perform the prescribed function of providing a cushioning material suitable for use in the intended applications. Mixtures of all of the aforementioned polymers can also be used to form the polymeric cushioning material.

In one preferred exemplary embodiment, the cushioning material is a polymeric material that has gel-like characteristics and is formulated as a blend of a polystyrene-poly (ethylene-ethylene/propylene)-polystyrene block copolymer (SEEPS) and oil, such as one or more mineral oils. A suitable gel-like cushioning material formed of a SEEPS copolymer/mineral oil blend is commercially available under the trade name PolyGel 51299 from PolyGel LLC of Whippany, N.J.

The cushioning material is also selected so that the cushioned liner **100** can be placed on the residual limb **130** in such away that the polymeric material does not drag against the skin. For example, it is desirable for the cushioned liner **100** to be capable of being rolled before the cushioned liner **100** is placed on the residual limb **130** and/or prosthetic device. Advantageously, the cushioning material is also designed to provide beneficial moisture to the residual limb **130** during the wearing of the cushioned liner **100**. Moreover, the cushioning material may include antioxidants, such as vitamins A, B, and C or any other antioxidants commonly used in polymers. In addition, skin conditioning agents can be added to the polymeric material of the cushioned liner **100** to soothe the skin of the residuum during wear. Such skin conditioners include mineral oil, baby oil, etc., which can be added to the polymeric material prior to its application to the sleeve member. Also, astringents, biocides, medicaments, etc., can be added or applied to the cushioning material to avoid infection or heal sores, etc.

The size of the cushioned liner **100** can be varied depending upon the dimensions of the residual limb to be enclosed by simply proportionally varying the dimensions of the pattern which is used to cut and form each of the first and second side panels **160**, **170** and the distal panel **180**. In other words, the length of the cushioned liner **100** of any of the embodiments disclosed herein can vary and the cushioned liner **100** can easily be manufactured in a number of different sizes by simply altering the dimensions of the patterns used to form the first and second fabric side panels **160**, **170** and the distal piece **180**. In one exemplary embodiment, the cushioned liner **100** has a length between about 8 inch to about 20 inch. Typically, the cushioned liner **100** is constructed to have a prescribed length and then the individual wearer's can modify the length of the cushioned liner **100** by simply cutting and removing an upper portion of the article. In this manner, the cushioned liner **100** can be initially produced to have a length that fits or can be easily modified to fit a large percentage of the potential customers.

As will be described in great detail hereinafter, the thickness of the cushioning material can vary along the interior surfaces **172**, **182** of the first and second side fabric panels **160**, **170** and the distal panel **180**, thereby permitting thickness variations in prescribed areas where additional cushioning is desired to provide added comfort and protection or where less cushioning is desired due to other practical considerations. The overall thickness of the cushioned liner **100**, that is the sum of the thickness of the textile liner body **110** and the thickness of the cushion layer **120**, is between about 2 mm and 19 mm, according to one exemplary embodiment. It will be understood that the foregoing measurements are merely illustrative and do not limit the scope of protection for the cushioned liner **100**. Thus, there may be particular applications where a thickness outside of the aforementioned range may be desired.

One exemplary process of applying the cushioning material to an article, such as the liner body **110**, is illustrated in FIGS. **7** through **15**. For purpose of illustration only, the present process will first be described with reference to the exemplary liner body **110**; however, it will be understood that any type of liner article can be used in place of the liner body **110**. In other words, conventional articles, including conventional liners can be used in the present process.

In this embodiment, the cushioning material is applied under pressure and is done in such a way that the thickness of the cushioning material can be controlled to a much greater degree of precision compared to conventional methods of applying the cushioning material, including the aforementioned dipping process. The thickness of the cushioning material can also be varied in select regions of the liner body so as to provide additional or less cushioning in the selected regions.

An apparatus **200** for applying the cushioning material under pressure to the interior **116** of the liner body **110** is illustrated in FIG. **7**. The apparatus **200** includes a base member **210** and a positionable mandrel **220**. The base member **210** has a cavity **230** formed therein and has a predetermined shape and predetermined dimensions that can be varied according to the precise application. The base member **210** has an upper surface **212** that is preferably planar in nature and the cavity **230** is defined by a surrounding structure **232**, which in the illustrated embodiment is a vertical housing that has a circumferential outer surface **234** and an inner surface **236** (cavity wall) that defines the cavity **230**. The vertical housing **232** thus has an open end **231** and an opposing closed second **233**.

In the exemplary embodiment, the base member **210** includes a first plate **227** which defines the upper surface **212** and a spaced second plate **229** with a number of legs **235** extending between the first and second plates **227**, **229** to support the first plate **227** relative to the second plate **229**. The vertical housing **232** extends between the first and second plates **227**, **229** and can extend through complementary openings formed in one or more of the first and second plates **227**, **229**. The vertical housing **232** preferably is arranged in a central location of both of the first and second plates **227**, **229** such that the legs **235** are located radially around the vertical housing **232**. It will be understood that a number of different constructions are possible for the base member **210** so long as the base member **210** includes the cavity **230**. The base member **210** can be formed of a number of materials so long as the material that defines the cavity **230** can be exposed to the elevated temperatures that are required to produce liquid or molten cushioning material without being damaged or otherwise impaired. Preferably, the base member **210** is formed of a metal material.

Optionally, the cavity **230** is communicatively connected to a vacuum source (not shown) such that the cavity **230** can be placed under a vacuum at select times during the process for applying the cushioning material to the liner body **110**. For example, a vacuum is preferably applied near or at the distal, closed end **233** of the cavity **230** to provide a force to assist the placement of the liner body **110** within the cavity **230**. More specifically, one or more vacuum ports (not shown) are formed in the vertical housing **232** and in communication with the cavity **230** at or near the distal closed end **233** thereof. A conduit (e.g., tubing) can connect the vacuum ports to the vacuum source. When the vacuum source is actuated, air is withdrawn through the vacuum ports, thereby resulting in a pressure reduction in the distal end of the cavity **230**. As will be described hereinafter, the liner body **110** is inserted into the cavity **230** such that the closed end **114** of the liner body **110** is inserted first and is positioned near or at the closed end **233** of the cavity **230**. Because it is desirable to open up the liner body **110** so that it assumes a more tube-like shape, the actuation of the vacuum source causes the fabric material of the liner body **110** to be pulled toward the cavity wall of the cavity **230**. The vacuum source thus serves to properly locate the liner body **110** within the cavity **230** (i.e., position and retain the closed distal end **114** of the sleeve member **110** at the closed end **233** of the cavity **230**).

The mandrel **220** is an elongated structure having a first end **221** and a second end **222** that is received within the cavity **230** during the process of applying the cushion material to the interior **116** of the liner body **110**. The exemplary mandrel **220** thus has a complementary shape relative to the cavity **230** so that at least a predetermined length of the mandrel **220** can be inserted into the cavity **230**. In one exemplary embodiment, the mandrel **220** has a generally annular cross-sectional shape with the second end **222** terminating in a smooth rounded portion.

The cross-sectional dimensions of the mandrel **220** are preferably not uniform from the first end **221** to the second end **222**. More specifically, the width of the mandrel **220** preferably varies along its length such that the mandrel **220** has a greater width near the first end **221** than at the second end **222**. The mandrel **220** can thus be thought of as having an inward taper from the first end **221** towards the second end **222**. While a number of different materials can be used to form the mandrel **220**, the mandrel **220** must be formed of a material that can withstand the elevated temperatures of the liquid or molten cushioning material (e.g., 300°–400°). In one exemplary embodiment, the mandrel **220** is formed of a metal material.

The first end **221** of the mandrel **220** is connected to a base **223** that in turn can be connected to a larger sized support platform **225** that is preferably dimensioned so that it extends across the first plate **227**.

The mandrel **220** is part of a system that includes a controller for adjusting the position of the mandrel **220** relative to the cavity **230**. In one exemplary embodiment, the mandrel **220** is pneumatically operated by a programmable control unit that adjusts the position of the mandrel **220**. In this embodiment, a pair of pneumatic cylinders **250** with drivable pistons **252** are disposed around the vertical housing **232** that includes the cavity **230**. First ends of the pistons **252** are connected to the support platform **225** such that when the pistons **252** are pneumatically driven, the pistons are either extended or retracted within the cylinders **250**, thereby causing relative movement of the support platform **225** and the mandrel **220** which is attached thereto. Because the mandrel **220** is axially aligned with the open end **231** of the cavity **230**, the retraction of the pistons **252** causes the mandrel **220** to be drawn into the cavity **230**.

Since the complete system is preferably a programmable computer controlled system, the precise coordinates of the mandrel **220** can easily be determined and monitored. Accordingly, the position of the mandrel **220** within the cavity **230** can be monitored.

Referring to FIG. **8**, the interior **116** of the liner body **110** is coated with the cushioning material in the following manner which ensures that the thickness of the cushioning material can be controlled with increase precision compared to conventional techniques. The liner body **110** is placed into the cavity **230** with the distal closed end **114** being inserted first into the cavity **230** and the liner body **110** is then properly located within the cavity, preferably by actuating the vacuum source to cause the liner body **110** to be drawn towards the cavity wall **236** of the cavity **230**. In this manner, the liner body **110** assumes a more tube-like shape with the side panels **160**, **170** be drawn apart from one another.

The cushioning material is heated to an elevated temperature that is above the point at which the cushioning material turns to a liquid or molten state and then the liquid or molten cushioning material is introduced into the inside of the liner body **110** by any number of conventional techniques, including injecting or otherwise feeding the cushioning material into the liner body **110**. As previously-mentioned, the entire system is preferably a programmable, computer controlled system which is capable of determining the amount of cushioning material that needs to be introduced into the liner body **110** in order to provide a cushioning layer **120** having a predetermined thickness. The amount of cushioning material that is introduced is determined based upon a number of factors including but not limited to, the dimensions of the sleeve member **110**, the dimensions of the mandrel **220**, the dimensions of the cavity **230**, etc.

As the cushioning material is added, it will pool within the inside of the liner body **110** at the closed distal end **114** thereof as best shown in FIG. **8**. The fabric material forming the liner body **110** is impermeable to the cushioning material and therefore, the cushioning material does not migrate from the interior **116** to the exterior **118**. In order to effectively coat the inside of the liner body **110** to a predetermined thickness, the mandrel **220** is introduced inside of the liner body **110** (FIG. **9**). The mandrel **220** is directed within the inside of the liner body **110** to a predetermined position where the distal end **222** of the mandrel **220** is disposed proximate to the closed distal end **114** of the liner body **110** (i.e., the distal end **222** is spaced a predetermined distance from the closed distal end **114**). It will be appreciated that as the mandrel **220** is moved into this preselected position, the distal end **222** contacts the pool of cushioning material and as the mandrel **220** is further driven towards the closed distal end **114**, the motion of the mandrel **220** causes the cushioning material to flow around the mandrel **220** as illustrated in FIGS. **10** and **11**. In effect, the cushioning material is forced up the sides of the mandrel **220** between the mandrel **220** and the inside surface of the liner body **110**. By carefully controlling the distance between the outer surface of the mandrel **220** and the interior surface of the liner body **110**, the precise thickness of the cushioning layer **120** can be controlled. In other words, the thickness of the cushioning layer **120** will necessarily be the distance between the outer surface of the mandrel **220** and the interior surface of the liner body **110**. However, the cushion material is slightly overpoured into the liner body **110** to ensure that a sufficient amount of cushion material is present to form the desired thickness of cushion layer **120**.

The amount of cushioning material that is introduced into the inside of the liner body **110** is preferably determined beforehand so that cushioning material is not wasted when the mandrel **220** is introduced into the liner body **110** to cause the cushioning material to be dispersed around the mandrel **220**. For example, if an excessive amount of cushioning material is disposed within the liner body **110**, the action of the mandrel will cause the cushioning material to be discharged from the cavity **230** since there is an excessive amount of cushioning material to fit within the space between the outer surface of the mandrel **220** and the interior of the liner body **110**.

The mandrel **220** can optionally include an extra safeguard to prevent the cushioning material from being discharged from the cavity **230**. For example, the mandrel **220** can include a movable sleeve (not shown) at or near the end **221** of the mandrel **220** that is positionable between a retracted position and an extended position where the sleeve covers the gap between the mandrel and the interior surface of the liner body **110**. In one exemplary embodiment, the movable sleeve is a spring-loaded ring that surrounds the mandrel **220** and is biased against the interior surface of the liner body **110**. The spring-loaded ring serves to prevent the cushioning material from flowing out of the cavity **230** since it extends across and seals off the passage where the cushioning material flows.

Once the mandrel **220** is driven to the preselected extended position to cause the cushioning material to flow around the mandrel **220**, the cushioning material is permitted to cool for a predetermined amount of time. This results in the cushioning material solidifying into the gel-like cushion layer **120**. After the cooling period has passed, the mandrel **220** is retracted from the cavity **230** with the cushioned liner **100** still being disposed over the mandrel **220** as illustrated in FIG. **12**. The cushioned liner **100** is then removed from the mandrel **220** by rolling the cushioned liner **100** off of the mandrel **220** as illustrated in FIG. **13**.

It will be appreciated that the application of a vacuum within the cavity **230** is not critical as it merely assists opening the liner body **110**. This process of applying the cushioning material offers a number of advantages over conventional methods since it provides a simple yet effective process for controlling the thickness of the cushion layer **120** to a greater degree of precision compared to conventional techniques. Because the distance between the mandrel **220** and the interior of the liner body **110** can be determined for any point along the mandrel **220** and the liner body **110**, the thickness of the cushion layer **120** is controlled since the thickness is defined by the distance between the mandrel **220** and the interior **116** of the liner body **110** when the exterior **118** of the liner body **110** is against the cavity wall **236** of the cavity **230**.

Referring to FIGS. **14** and **15**, it will also be appreciated that the inside contour of the cushion layer **120** (i.e., the interior **116** of the cushioned liner **100**) is controlled by the contour of one or more of the mandrel **220** and the cavity **230**. In one embodiment, the mandrel **220** is customized for a given application by altering the shape of the mandrel **220** along its longitudinal axis. For example, the mandrel **220** can include a recessed section along its length and when the mandrel **220** is introduced into the cavity **230** and the cushion material flows around the mandrel **220**, the cushion material will settle within the recessed section of the mandrel **220**. Because the distance between the recessed section and the liner body **110** is greater than the distance between surrounding portions of the mandrel **220** and the liner body **110**, the thickness of the cushion layer **120** is greater in this section. Thus, a localized area of the interior **116** of the liner body **110** is formed to a greater thickness than surrounding sections. Preferably, this localized area of increased thickness is formed in an area where extra cushion is desired to provide additional comfort to the wearer as is the case in some of the sensitive interface locations between the residual limb **130** and the prosthetic device, etc. For example, the front portion of the cushioned liner **100** and distal end **114** are regions where additional comfort is desired since these regions (i.e., the shin area and distal stump area) correspond to sensitive areas of the residual limb **130**. The amount of cushion material at the distal end **114** is controlled by the distal shape of the mandrel **220** and by the final position of the mandrel **220** relative to the distal end **114** of the liner body **110** (i.e., the greater the distance between the mandrel and the distal end **114**, the greater the thickness of the cushion layer **120**).

It will be appreciated that the mandrel **220** can be contoured in any number of different ways depending upon the desired contour of the cushion layer **120** of the cushioned liner **100**. For example, the inward taper of the mandrel **220** can be non-uniform in manner to produce variations in thickness along the interior **116** of the cushioned liner **100**. This embodiment is generally shown in FIGS. **14** and **15** in which a mandrel **220'** is illustrated. The mandrel **220'** is similar to the mandrel **220** with the exception that the distal end portion of the mandrel **220'** has a non-uniform cross-sectional shape. More specifically, one section of the distal end portion has a pronounced taper **250**. In this section having a pronounced taper **250**, the distance between the mandrel **220** and the liner body **110** is greater than in other surrounding sections and therefore, additional cushioning material is permitted to flow and ultimately cool and form the cushion layer **120** in this area. FIG. **15** clearly shows that the incorporation of the pronounced taper **250** into the mandrel **220** results in the cushioned liner **100** having one section (e.g., a front shin portion thereof) that has additional cushioning material provided thereat so as to provide the wearer with added comfort and protection in this sensitive area.

It will be appreciated that the mandrel **220** can be modified in any number of different ways to selectively control the thickness in localized areas of the cushioned liner **100**. For example, the distal end **222** of the mandrel **220** can have an annular recessed section that receives additional cushioning material, thereby altering the thickness profile at the distal end **114** of the cushioned liner **100**.

If an area of reduced thickness is desired, the mandrel **220** can be modified to include one or more protruding features (i.e., a section of the outer surface of the mandrel **220** that protrudes outwardly relative to the surrounding sections of the mandrel **220**). Each protruding feature reduces the distance between the mandrel **220** and the interior of the liner body **110** and thus causes the cushion layer **120** to have a reduced thickness in this region.

In another aspect, the cavity **230** does not necessarily have to have a uniform shape; but rather, the cavity **230** can be formed to have any number of shapes. By altering the contour of the cavity **230**, the thickness of the cushion layer **120** of the cushioned liner **100** can be varied in select locations. For example, the cavity wall of the cavity **230** can include a recessed section or a protruding section to cause the liner body **110** assume a different shape in this section.

Thus, it will be understood that the present process permits a number of different cushioned liners **100** to be produced using a limited amount of equipment since the mandrel **220** is interchangeable and one mandrel **220** having one profile can be interchanged for another mandrel **220** having another profile. By interchanging the mandrel **220** and maintaining the same cavity **230**, the thickness and contour of the cushion layer **120** can be controlled to a high degree of precision. Further, the present process is less complicated than the conventional methods, including the dipping method, as it does not require a series of steps to build-up the cushion layer **120** to the desired thickness nor does it require that the cushioned liner **100** be inverted after the cushion layer **120** is formed on the interior of the liner body **110**.

The present process of using compression molding techniques to apply a cushion layer to the liner body is not limited to being merely used to produce cushioned liners (i.e., prosthetic liners) but rather, the present process can be used to produce other articles, including cushion or gel products that do not contain a fabric component and also other products, such as cushioning pads that can be incorporated into socks and other products to be worn on one of the various limbs of the body, i.e., an elbow pad. The cushioned pad products can include a fabric layer (liner) on one side or both sides.

In another embodiment, a cushion article (i.e., a pad) (not shown) is formed without a fabric backing layer (i.e., liner body **110**). In other words, the article is formed entirely of cushioning material that is molded to have a predetermined, desired shape. The article is preferably formed using the apparatus shown in FIGS. **7–15**. In this embodiment, the liner body **110** is not introduced into the apparatus **200** and more specifically, the cushioning material is disposed in the cavity **230** such that the cushioning material pools at the closed distal end of the cavity **230**. The mandrel **220** is then introduced into the cavity **230** and driven towards the distal end **233** of the cavity **230**. As the mandrel **220** is driven to its fully extended position, it compresses the pool of cushioning material, causing the cushioning material to flow around the outer surface of the mandrel **220**. As previously-described in detail, the thickness of the article is controlled by the distance between the mandrel **220** and the wall **236** of the cavity **230**. Because this distance can be carefully and precisely controlled, the thickness of the article can likewise be precisely controlled.

The article is thus formed between the outer surface of the mandrel **220** and the wall **236** of the cavity **230**. After the cushioning material has been sufficiently cooled, the mandrel **220** is retracted from the cavity **230** with the article still being coupled to (i.e., surrounding) mandrel **220**. The article is then rolled or otherwise removed from the mandrel **220**. The article can be formed to have any number of shapes and sizes by varying the size and shape of at least one of the mandrel **220** and the cavity **230**. For example, article can be constructed to act as a resilient cushioning member that can be fitted around a toe or finger.

Now referring to FIGS. **16–23**, FIG. **16** shows another exemplary article **400** that can be formed using the compression molding process disclosed herein. In this embodiment, an apparatus **500** is used to form the article **400**. The apparatus **500** shares some similarities with the apparatus **200**. The apparatus **500** includes a mold body **510** having a recessed mold cavity **512** for receiving the cushioning material and optionally, one or more fabric layers. The apparatus **500** also includes a positionable mandrel plate **520** for dispersing the cushioning material under compression across the cavity **512** so that the cushioning material spreads across the cavity **512** and is formed to a predetermined thickness. In this embodiment, the mandrel plate **520** has a recessed portion **522** that receives the liquid or molten cushioning material and at least partially defines the shape of the article **400**. As shown in FIG. **18**, the mandrel plate **520** fits intimately within the cavity **512** such that a peripheral edge of the mandrel plate **520** seats against the cavity floor and the cushioning material is forced into the recessed portion **522**.

After the cushioning material has sufficiently cooled, the mandrel plate **520** is retracted and the article **400** is removed from the recessed section **522** as illustrated in FIG. **19**.

FIG. **20** illustrates another exemplary article **530**. The article **530** is similar to the article **400** with the exception that the article **530** includes an integral ridge **534** that extends the length of the article **530**. As illustrated in FIGS. **21–23**, to form the article **530**, the apparatus **500** is simply modified by forming a recessed feature **540** in the recessed section **522** of the mandrel plate **520**. In this embodiment, the feature is a semi-circular recessed groove to form the semi-circular ridge shown in FIG. **20**. The formation of the article **530** is then conducted in essentially the same manner as described above.

FIG. **22** shows another feature of the apparatus **500** in that the mandrel plate **520** includes one or more ports **550** that act as ports for releasing excess cushioning material and for releasing air, etc. from the mold cavity. Because the cushioning material preferably has a gel-like consistency, only excess cushioning material is forced through the ports **550** when compressive forces are applied to the cushioning material by the mandrel plate **520**. The ports **550** also function to evacuate air and this decreases the chance that the formed cushioned article will have air bubbles, other imperfections, etc. The excess material can be directed to any number of locations, including the sides of the plate or the top of the mandrel plate **520**. FIG. **23** shows the removal of the article **530**.

FIG. **24** shows another exemplary article **600** that can be formed using the compression molding process disclosed herein. In this embodiment, the article **600** is generally in the form of a pad of cushioning material. The pad **600** can assume any number of shapes and can also be provided in any number of dimensions. In one embodiment, the pad **600** is disposed on a bottommost foot portion of a sock **610** such that the pad **600** extends from the heel portion **612** to the toe portion **614**. The sock **610** can be a standard athletic sock or any other type of sock (e.g., a diabetic sock). Optionally, a fabric protective sheet **620** is securely attached to the pad **600** and serves as the ground contacting surface when the sock **610** is worn.

The sock **610** is formed using a compression molding process that is similar to the process described hereinbefore. FIG. **25** illustrates an apparatus **700** for making the pad **600** using compression molding techniques. The apparatus **700** includes a mold body **710** having a recessed section (e.g., cavity) **712** for receiving the cushioning material and a backing article in some embodiment and a positionable mandrel plate **720** for dispersing the cushioning material under compression across the recessed section **712** so that the cushioning material spreads out across the recessed section **712** and has a predetermined thickness.

FIG. **25** shows another feature of the apparatus **700** in that the mold body **710** includes one or more ports **722** for releasing excess cushioning material. The ports **722** also function to evacuate air and this decreases the chance that the formed cushioned article will have air bubbles, other imperfections, etc. In the illustrated embodiment, the ports **722** are orientated at one end of the recessed section **712**; however, it will be understood that the ports **722** can be arranged in any number of locations within the recessed section **712**.

The mold body **710** preferably includes side sections **714**, **716** that extend laterally from the body portion containing the recessed section **712**. The side sections **714**, **716** can further include apertures **718** or the like which receive complementary locating features **719** formed on the mandrel plate **720** so as to assist in locating and retaining the mandrel plate **720** against the mold body **710**. The mandrel plate **720** is an elongated member that includes a block portion **730** that is configured to be received within the recessed section **712**. Thus, the block portion **730** is formed on the mandrel plate **720** at a location such that when the mandrel plate **720** is closed relative to the mold body **710**, the block portion **730** is received within the recessed section **712**. The block portion **730** therefore has a complementary shape and complementary dimensions relative to the recessed section

712 to permit mating between the two. The mandrel plate 720 also preferably includes the locating features 719 (e.g., locating pins protruding downwardly from the mandrel plate 720) that are received in the apertures 718 when the mandrel plate 720 is mated with the mold body 710.

The apparatus 700 also includes means for mating the mandrel plate 720 with the mold body 710 under compressive forces. More specifically, any number of conventional means can be used for applying a compressive force to the mandrel plate 720 when it is properly aligned and mated with the mold body 710. The application of compressive forces to the cushioning material disposed within the recessed section 712 causes the cushioning material to be uniformly dispersed throughout the recessed section 712. In one embodiment, the means for applying compressive forces can be a pneumatic device that extends and retracts the mandrel plate 720 relative to the mold body 710, similar to the embodiment of FIGS. 7–15. In another embodiment, the means can consist of a manually driven press device where an operator engages the mandrel plate 720 and applies a force against the mandrel plate 720 to cause compression and dispersement of the cushioning material within the recessed section 712.

The recessed section 712 can be formed to have a number of different shapes and also, as illustrated, the recessed section 712 can have beveled edges 713 that define the periphery of the recessed section 712. The beveled edges 713 cause the molded product to have beveled edges.

The process of forming an article, such as pad 600, using the apparatus 700 is as follows (with reference to FIGS. 25–28). The mandrel plate 720 is initially separated from the mold body 710 and the cushion material is injected or otherwise disposed within the recessed section 712 as shown in FIG. 26. When it is desired for the pad 600 to be formed as part of an article, such as sock 610, the article can be disposed can be disposed either in the cavity 712 to formed the pad 600 on top of the article or the article can be disposed around the block portion 530 to form the pad 600 underneath the pad 600, or articles can be disposed at both locations to form the pad 600 between two articles.

A robotic injector or the like can be used to inject a predetermined amount of cushioning material (in a liquid or molten state) into the recessed section. Preferably, the amount injected is slightly more than amount needed to form the article (in other words an overflow amount of cushioning material is injected). After the cushioning material has been injected, the mandrel plate 720 is then positioned such that the block portion 730 is aligned with and received within the recessed cavity 712. Compressive forces are applied to the mandrel plate 720 causing the block portion 730 to contact and apply a compressive force against the cushioning material that is disposed within the recessed section 712, as illustrated in FIG. 27. The block portion 730 thus effectively disperses the cushioning material across the recessed cavity 712 as the mandrel plate 720 is driven to a closed position. In the closed position, the mandrel plate 720 and the mold body 710 fully mate with one another and the distance between the block portion 730 and the surface of the recessed section 712 define the thickness of the product that is formed within the recessed section 712. Likely, as the mandrel plate 720 is driven to this closed position, some of the cushioning material (i.e., the excess amount) is driven through the ports 722 (which can be in the mold body 710 and/or the mandrel plate 720).

The cushioning material is then allowed to sufficiently cool before the mandrel plate 720 is retracted from the closed position and access is provided to the recessed section 712. Once the mandrel plate 712 is separated from the mold body 710, the article (e.g., pad 600) is removed.

The apparatus 700 includes a number of the features that are contained in the apparatus 200. More specifically, both apparatuses are configured to offer improved control over the degree of precision in forming an article of a desired thickness. Further, both apparatuses permit the contour/profile of the formed article to be readily altered depending upon the precise application and the desired characteristics that the operator wishes the article to include.

It will be appreciated that one or more characteristics of at least one of the block portion 730 and the recessed section 712 can be altered, thereby causing the formed article to have an altered profile. For example, while traditional manufacturing methods produce gel-like pads having planar surface, the present apparatus and process permit the top and/or bottom surface of the article to have an non-uniform appearance. In one embodiment, the block portion 730 does not contain a uniform shape but rather contains one or more non-uniform features, such as a protruding section or a recessed section.

When it is desired to form the cushion layer on a surface of an article, such as the sock 610, the above described process is slightly modified in that the sock 610 is preferably placed around the block portion 730 and the cushioning material is injected into the cavity 712 and then the mandrel plate 720 is compressed causing the cushioning material to be dispersed across the sock 610 as shown in FIG. 27. Upon cooling and disengagement of the mandrel plate 720, the cushioned pad 600 is formed on the sock 610. If it is desired that the cushioned sock article contain the fabric protective sheet 620, the fabric protective sheet 620 is disposed in the cavity 712 and the sock 610 is disposed around the block portion 730, and the mandrel plate 720 is fully extended such that the block portion 730 compresses the cushion material between the sock 610 and the sheet 620 as shown in FIG. 28. The above process is not limited to being used in combination with a sock but rather applies to any application where one or more fabric elements are formed with the pad 600. It will be appreciated that the fabric element can initially be releasably adhered to the block portion 730 so as to ensure the proper positioning of the fabric element within the recessed section 712.

In yet another embodiment illustrated in FIG. 29, an interchangeable cast member 800 is disposed within the recessed section 712. The cast member 800 includes a peripheral edge 802 that preferably is complementary to the peripheral edge of the recessed section 712 so that when the cast member 800 is inserted into the recessed section 712, the peripheral edge 702 is seated against the peripheral edge of the recessed section 712 such that the cast member 800 is securely retained within the recessed section 712 and does not move unnecessarily. The cast member 800 has a shaped opening 810 formed therethrough for receiving the cushioning material. It will be understood that the shaped opening 810 defines the shape of the cushioned article that is formed as a result of disposing the cushioning material within the shaped opening 810. It will further be understood that the block portion 730 must also be configured in a complementary manner such that the block portion 730 is received within the shaped opening and causes the cushioning material to be dispersed throughout the shaped opening 810.

One particular use of the cast member 800 is described with reference to FIGS. 30–32. FIG. 30 illustrates an article 900. Article 900 is preferably formed of a textile material (i.e., fabric, etc.) and includes a first portion **910** that is free of cushioning material and a second portion **920** which includes cushioning material formed in the shape of a pad **930** or the like. The article **900** is formed by first placing the article **900** in the recessed section **712** of the mold body **710**. The article **900** is spread out so that it remains flush against the bottom surface of the recessed section **712**. The cast member **800** is then inserted into the recessed section so that the peripheral edge **802** seats against the peripheral edge of the recessed section **712**. The shaped opening **810** is thus positioned over only a section of the article **900** and the surrounding sections of the article **900** that lie underneath the cast member **800** are not exposed to the cushioning material.

The cushioning material is injected into the shaped opening **810** and the mandrel plate **720** is then closed, whereby the block portion **730** is received within the shaped opening **810** and compresses the cushioning material. Preferably, one or more ports **722** is in communication with the shaped opening **810** to permit any excess cushioning material and/or air to be discharged from the shaped opening **810**. Thus, ports **722** formed in the body **710** and the cast member **800** are axially aligned. The ports **722** can also be formed in the block portion **730**. Because the article **900** is disposed across the bottom of the shaped opening **810**, the pad **930** is formed on top of the second portion **920** of the article **900**. After cooling, the mandrel plate **720** is retracted and the cast member **800** can be removed, leaving the article **900** having the pad **930** formed thereon. As with the other embodiments, the pad **930** does not have to have a planar top or bottom surface. The block portion **730** can have a non-uniform shape, e.g., it can contain a recessed section to produce a section of increased cushion thickness or it can contain a protruding feature to reduce the thickness in a localized area of the article. The peripheral edge of the article can be shaped by contouring the shape of the peripheral edge of the cast member **800** that defines the shaped opening **810**.

As with the other embodiment, the recessed section **712** and the cast member **800** can be used to produce a cushion pad that is not a part of or coupled to another article (e.g., a fabric). The cushion pad can be distributed for later attachment to an article or the cushion pad can be used by itself (i.e., around a toe or finger).

As is the case with all of the embodiments, the apparatus **700**, with or without the use of the cast member **800**, permits the thickness of the cushion pad to be controlled with improved precision since the distance between the block portion **730** and the recessed section **712** can be readily determined and controlled. Further by interchanging the components, the profiles of the block portion **730** and/or the recessed section **712** can be varied, thereby changing the profile of the formed cushion article.

It will be appreciated that the disclosed compression molding apparatuses can be used to produce a number of different types of articles and those articles disclosed herein are merely exemplary in nature and not limiting of the scope of the present disclosure. The present application thus discloses cushioned sleeve members that advantageously are constructed so that the interface between the residual limb and the prosthetic device is improved by eliminating the distal seam that extends across the sensitive distal end of the residual limb. Further, the present application provides methods that permit the thickness of the cushion layer to be controlled with enhanced precision and also permits the profile (contour) of the cushion layer to be readily changed.

While the invention has been particularly shown and described with reference to preferred embodiments thereof, it will be understood by those skilled in the art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

What is claimed is:

1. A process for forming a final molded article in the form of a cushion layer of a preselected thickness on an inside of a prosthetic liner body, the process comprising the steps of:

providing an apparatus including a mold having a cavity formed therein and a mandrel that is positionable between a retracted position and an extended position, wherein in the extended position, at least a portion of the mandrel is received within the cavity, wherein the distance between a first point alone an inner surface of the mold cavity and a second point along an outer surface of the mandrel when it is disposed therein represents a thickness of the final molded article, wherein the distance is measured along an axis that extends only across an empty space formed between the inner and outer surfaces;

disposing the prosthetic liner body into the mold cavity;

disposing a quantity of cushioning material, in its liquid state, into the inside of the prosthetic liner such that the cushioning material pools at a distal end of the prosthetic liner, the quantity being a sufficient quantity to form the cushion layer of the preselected thickness, wherein the cushioning material comprises a thermoplastic elastomer that forms the final molded article and is selected so that the cooled resulting final molded article can be freely rolled off the mandrel;

directing the mandrel into the inside of the prosthetic liner until the mandrel is positioned in the extended position, the driving action of the mandrel causing the cushioning material to be dispersed between the mandrel and the prosthetic liner, thereby forming the cushioning layer of the preselected thickness;

cooling the cushioning material to form a cushioned prosthetic liner; and

withdrawing the mandrel from the mold cavity such that the final molded article can be removed therefrom.

2. The process of claim **1**, wherein at least a distal end of the mold cavity is in communication with a vacuum source such that a vacuum is selectively applied to the mold cavity to assist in positioning of the prosthetic liner body.

3. The process of claim **1**, wherein the positionable mandrel is part of a programmable pneumatic device which drives the mandrel between the retracted position and the extended position.

4. The process of claim **3**, wherein the mandrel is an elongated structure supported at one end with a base, the base being connected to two or more pistons of pneumatic cylinders for pneumatically driving the mandrel between the retracted position and the extended position.

5. The process of claim **1**, wherein in the retracted position, the mandrel is spaced a predetermined distance from the prosthetic liner body, the predetermined distance corresponding to the preselected thickness of the cushioned prosthetic liner.

6. The process of claim **1**, wherein the mandrel comprises an elongated structure having a first supported end and an opposing rounded distal end.

7. The process of claim **6**, wherein the mandrel tapers inwardly along a length thereof from the first end to the rounded distal end.

8. The process of claim **1**, further including the step of:

contouring the cushion layer by altering a surface of the mandrel.

9. The process of claim **1**, wherein the mandrel has a non-uniform shape.

10. The process of claim **1**, further including the step of:

forming a recessed section along the length of the mandrel, the recessed section causing the formation of a section of increased thickness along the length of the cushion layer of the cushioned prosthetic liner.

11. The process of claim **1**, further including the step of:

forming a protruding section along the length of the mandrel, the protruding section causing the formation of a section of decreased thickness along the length of the cushion layer of the cushioned prosthetic liner.

12. The process of claim **1**, wherein the mandrel has an uneven taper along its length in that a section of the distal end has an increased taper relative to surrounding sections of the distal end.

13. A process for forming a cushion layer of a preselected thickness on an inside of prosthetic liner body, the process comprising the steps of:

providing an apparatus including a mold having a cavity formed therein and a mandrel that is positionable between a retracted position and an extended position, wherein in the extended position, at least a portion of the mandrel is received within the cavity;

disposing the prosthetic liner body into the mold cavity;

disposing a quantity of cushioning material into the inside of the prosthetic liner such that the cushioning material pools at a distal end of the prosthetic liner, the quantity being a sufficient quantity to form the cushion layer of the preselected thickness;

directing the mandrel into the inside of the prosthetic liner until the mandrel is positioned in the extended position, the driving action of the mandrel causing the cushioning material to be dispersed between the mandrel and the prosthetic liner, thereby forming the cushioning layer of the preselected thickness; cooling the cushioning material to form a cushioned prosthetic liner; and

withdrawing the mandrel from the mold cavity such that the cushioned prosthetic liner can be removed therefrom, wherein the mandrel includes a spring-based element at or proximate to the first end, the spring-biased element being a ring-shaped element surrounding the mandrel and being biased against the prosthetic liner body so as to enclose the space between the mandrel and the prosthetic liner body, thereby preventing cushioning material from being discharged from the cavity.

14. The process of claim **1**, wherein the cushioning material is a gel composition.

15. The process of claim **14**, wherein the gel composition comprises a block copolymer and mineral oil.

16. The process of claim **15**, wherein the block copolymer is a polystyrene-poly(ethylene-ethylene/propylene)-polystyrene (SEEPS) block copolymer.

17. The process of claim **1**, wherein the mandrel has a substantially conical cross-sectional shape.

18. A process for forming an article formed of a layer of cushioning material that has a preselected thickness, the process comprising the steps of:

providing an apparatus including a mold having a cavity formed therein and a mandrel that is positionable between a retracted position and an extended position, wherein in the extended position, at least a portion of the mandrel is received within the cavity;

disposing a prosthetic liner body having at least two fabric pieces, one of the fabric pieces being a distal end piece that is attached to at least one other fabric piece along a circumferential edge of the distal end piece, the distal end piece being free of a transverse seam extending across the distal end piece, into the mold cavity, the distal end piece being disposed at one end of the at least one other fabric piece and having a substantially annular shape prior to and after attachment to the at least one other fabric piece;

disposing a quantity of cushioning material into an inside of the prosthetic liner such that the cushioning material pools at a distal end of the prosthetic liner, the quantity being a sufficient quantity to form the cushioning layer of the preselected thickness;

directing the mandrel into the inside of the prosthetic liner until the mandrel is positioned in the extended position, the driving action of the mandrel causing the cushioning material to be dispersed between the mandrel and the prosthetic liner, thereby forming the cushioning layer of preselected thickness;

cooling the cushioning material to form the cushioning layer; and

withdrawing the mandrel from the mold cavity such that the article can be removed therefrom.

19. The process of claim **18**, wherein the positionable mandrel is part of a programmable pneumatic device which drives the mandrel between the retracted position and the extended position.

20. The process of claim **19**, wherein the mandrel is an elongated structure supported at one end with a base, the base being connected to two or more pistons of pneumatic cylinders for pneumatically driving the mandrel between the retracted position and the extended position.

21. The process of claim **18**, wherein in the retracted position, the mandrel is spaced a predetermined distance from an inner wall of the prosthetic liner, the predetermined distance corresponding to the preselected thickness of the cushioning layer.

22. The process of claim **18**, wherein the mandrel comprises an elongated structure having a first supported end and an opposing rounded distal end.

23. The process of claim **22**, wherein the mandrel tapers inwardly along a length thereof from the first end to the rounded distal end.

24. The process of claim **18**, further including the step of:

contouring the article by altering a surface of the mandrel.

25. The process of claim **18**, wherein the mandrel has a non-uniform shape.

26. The process of claim **18**, further including the step of: forming a recessed section along the length of the mandrel, the recessed section causing the formation of a section of increased thickness along the length of the article.

27. The process of claim **18**, further including the step of: forming a protruding section along the length of the mandrel, the protruding section causing the formation of a section of decreased thickness along the length of the article.

28. The process of claim **18**, wherein the mandrel has an uneven taper along its length in that a section of the distal end has an increased taper relative to surrounding sections of the distal end.

29. The process of claim **18**, wherein the cushioning material is a gel composition.

30. The process of claim **29**, wherein the gel composition comprises a block copolymer and mineral oil.

31. The process of claim **30**, wherein the block copolymer is a polystyrene-poly(ethylene-ethylene/propylene)-polystyrene (SEEPS) block copolymer.

32. The process of claim 18, wherein in the extended position, there is a gap between a distal end of the mandrel and a-closed distal end of the prosthetic liner, the cushioning material settling within this gap and flowing around an outer surface of the mandrel so as to form a tube-like article having a closed distal end.

33. A process for forming an article formed of a cushioning material and having a preselected thickness, the process comprising the steps of:

providing an apparatus including a mold having a cavity formed therein and a mandrel plate that at least includes a mandrel block that is adapted to be received within the mold cavity;

disposing a fabric layer to a bottom surface of the cavity;

inserting a cast member into the cavity, the cast member having a through opening formed therein for receiving the cushioning material, wherein the shape of the article is controlled by a shape of the through opening, the cast member being disposed on top of the fabric layer such that the fabric layer is exposed in an area of the through opening the mandrel block having a shape complementary to the through opening to permit the mandrel block to be received in the through opening;

determining the preselected thickness of the article and disposing a sufficient quantity of cushioning material into the cast member to form the article to the preselected thickness, the cushioning material pooling within the cast member;

directing the mandrel block into the inside of the cast member so that the mandrel block contacts the cushioning material and spreads the cushioning material throughout the cast member, the mandrel block being driven to an extended position where the distance between a bottom surface of the mandrel block and the fabric is approximately equal to the preselected thickness;

cooling the cushioning material to form the cushioning layer; and

withdrawing the mandrel block from the cast member such that the article can be removed therefrom.

34. The process of claim 33, wherein the mandrel block has an outer dimensions that is about equal to an inner dimension of the cast member so that a peripheral edge of the mandrel block is in intimate contact with a peripheral edge of a wall that defines the through opening, thereby preventing cushioning material from flowing between the mandrel block and the wall that defines the through opening.

35. The process of claim 33, wherein the mandrel block and the cast member have complementary shapes selected from the group consisting of: circles, ovals, squares, rectangles, diamonds, and triangles.

36. The process of claim 33, wherein the step of driving the mandrel comprises the steps of:

manually closing the mandrel plate such that the mandrel block is received within the through opening; and

applying a compressive force against the mandrel block which is transferred to the cushioning material to cause the cushioning material to spread across the cast member.

37. The process of claim 33, wherein the step of driving the mandrel comprises the step of:

pneumatically closing the mandrel plate such that the mandrel block is received within the through opening, the mandrel block being driven to the extended position, whereby a compressive force is applied to the cushioning material to cause the cushioning material to spread across the cast member.

38. The process of claim 33, further including the step of:

disposing a first fabric layer to a bottom surface of the cavity prior to disposing the cushioning material into the cavity, and

disposing a second fabric layer around the mandrel block prior to driving the mandrel block to the extended position, the cushioning layer being formed between the first and second fabric layers.

39. The process of claim 33, further including the step of:

forming a discharge port in the mold such that the discharge port is in communication with the cast member and permits at least one of excess cushioning material and air to be evacuated from the cast member.

40. The process of claim 33, further including the step of:

forming a discharge port in the mandrel block such that the discharge port is in communication with the cavity and permits at least one of excess cushioning material and air to be evacuated from the cavity.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 6,852,269 B2
DATED : February 8, 2005
INVENTOR(S) : John D. Eberle et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 22,
Line 20, after "cavity", -- ,the liner body being formed of at least two separate fabric pieces, one of the fabric pieces being a distal end piece that is attached to at least one other fabric piece along a circumferential edge of the distal end piece, the distal end piece defining a closed end of the liner body and being free of a transverse seam extending acrosss the distal end piece -- has been inserted.

Column 24,
Line 6, after "piece", -- to define a closed end of the liner body -- has been inserted;
Lines 6-7, "annular" has been replaced with -- circular --;

Signed and Sealed this

Tenth Day of May, 2005

Jon W. Dudas

JON W. DUDAS
Director of the United States Patent and Trademark Office